

REQUEST FOR PROPOSAL

May 25, 2007 Grants Management System RFP# CIRM 2060

You are invited to review and respond to this Request for Proposal (RFP), entitled RFP#CIRM 2060 Grants Management System for the California Institute for Regenerative Medicine (CIRM). Please read the instructions carefully before preparing and submitting your proposal. Missing and/or incomplete information may cause your response to be disqualified from further consideration. The CIRM seeks qualified firms with expertise in grants management systems to submit proposals for a Grant Application & Management System described in Section A, 2.

In the opinion of the CIRM, this RFP including all attachments and exhibits, is complete and provides all the information and criteria necessary to submit a competitive proposal. If you have questions, however, or should you need any clarifying information, the contact person for this RFP is:

Ed Dorrington Contract Manager (415) 396-9108

All submittals must be received on or before 5 PM Pacific Time, June 22, 2007. Submit one copy of the proposal electronically in PDF format to: edorrington@cirm.ca.gov. Return four identical hard copies (one original signed and three identical copies) to:

California Institute for Regenerative Medicine 210 King Street San Francisco, CA 94107 Attn: Edward Dorrington (415) 396-9108

Faxed submittals will not be accepted Late submittals will not be accepted

Please note that no *verbal* information that is given will be binding upon the State unless such information is issued in writing as an official addendum to this RFP.

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A. Purpose and Description of Services

1. Introduction

The California Institute for Regenerative Medicine (CIRM) was established for the purpose of making grants and loans to California's universities and other advanced medical research facilities throughout the state for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and/or medical procedures that will result in, as speedily as possible, the cure for, and/or substantial mitigation of, major diseases, injuries, and orphan diseases. Priority will be given to stem cell research that has the greatest potential for therapies and cures, specifically focused on pluripotent stem cell and progenitor cell research among other vital research opportunities that cannot, or are unlikely to, receive timely or sufficient federal funding. Funding for the grants and loans and for the operational costs necessary to accomplish this purpose will come from the issuance by the State Treasurer of \$3 billion in general obligation bonds. The grant and loan funding decisions will be made by the Independent Citizens' Oversight Committee (ICOC), a twenty-nine member body charged with governing the CIRM. The ICOC is authorized under Proposition 71 of 2004 to commit an average of \$295 million per year in grants and loans over a 10-year period. In addition, the ICOC is authorized to accept real and personal property donations to fund operations and grant programs. Also, the ICOC is authorized to accept general fund loans to finance start up activities for CIRM or to provide bridge financing until the bonds are sold. Finally, the State Treasurer may issue Bond Anticipation Notes (BANS) as bridge financing.

The CIRM is requesting a proposal for a Grants Management System and seeks to contract with a qualified firm experienced in grants application and management systems.

The firm that is selected must be technically and professionally capable of providing the services in all subject areas described in Section A, Item 2, Scope of Services and meet the Minimum Qualifications for Proposers in Section B. The firm must be free from actual conflicts of interest not only at the time of selection, but also throughout the term of the contract.

The CIRM expects that the winning firm will be able to start the project shortly after the execution of the contract. The CIRM anticipates entering into a one year contract for Phase 1 with a possible one month extension.

2. Scope of Services

The Grants Management System firm will be expected to provide the CIRM with services as described herein:

b) Scope of Work

1. See Functional Requirements Document, Exhibit 1.

c) Budget and Timeline

1. An all-inclusive competitive cost proposal shall include all administrative expenses and travel on a "not-to-exceed" basis.

2. We expect the timeline and budget to consist of two distinct phases:

Phase I. Development, design, implementation, and integration. A detailed timeline for the successful completion of a grants application and management system rollout.

Licensing Fees and/or customization, development and integration costs on a pay for performance not to exceed basis, based on the deliverables and timeline outlined in (e) below. Each payment will hold back of 10% to be disbursed at the completion of the project.

Phase II. Annual maintenance fees, hosting fees and upgrade fees listed individually.

d) Deliverables

The following table outlines at a high level the deliverables for the project.

Description	Due Date	Frequency
Project Schedule, showing project tasks, milestones and progress against the tasks, unexpected occurrences, etc.	10 days after contract award, the 10 th of each month thereafter	Monthly
Project Status Report, explaining progress thus far, issues, risk factors, etc.	The 10 th of each month	Monthly
User Manual	Concurrent with capability delivered	As required
System Description, illustrating system components and their interconnections	30 days after contract award	As required
Maintenance Plan, showing the tasks and schedules required to maintain the system	45 days after contract award.	As required
Quarterly project status meetings, face-to-face or teleconference meetings to discuss project issues and status.	90 days after contract award, quarterly thereafter	Quarterly
Final System Documentation	Concurrent with the end of project	One-time
User training session, to acquaint CIRM staff with the newly delivered capability	Concurrent with capability delivered	As required

e) Projected Timeline

The following table outlines the roll-out order and timing which best suits CIRM's requirements. Respondents may include a modified timeline and/or order in their proposals, but any variation must be documented and explained.

Functionality as defined in Exhibit 1, Functional Requirements (FR)	Availability Date	Proposed payment Percent of Contract Value ¹
Project Start	7/16/2007	
Grants Management (FR4, parts of FR1 and FR7)	9/17/2007	
Progress Reporting (FR5, parts of FR1 and FR7)	10/22/2007	
Application (FR2, parts of FR1 and FR7)	11/12/2007	
Reporting (FR6, parts of FR1 and FR7)	12/3/2007	
Review (FR3, parts of FR1 and FR7)	12/31/2007	
Import of legacy data	1/7/2007	
Final rollout (any remaining functionality) w/ final systems documentation	1/14/2008	

f) Report and Presentation

The successful consultant will be required to meet with the CIRM Scientific Team and the Director of Grants Management Systems to make presentations both at the initiation of the contract and throughout the contract, as needed. These meetings will take place either as in-person meetings, or as conference calls. Inperson meetings will not take place more than quarterly, and all expenses involved in these meetings must be accounted for within the proposed budget. CIRM further expects ongoing and open communications with the consultant over the course of the contract.

B) Minimum Qualifications for Proposer(s)

The CIRM expects to have a close working relationship with its grants management system vendor as evidenced by the nature of the tasks listed above, and requires the demonstration of a high degree of experience, training and proficiency in the conduct of the various functions performed. The grants management system firm should have an extensive history in grants and application management systems. In addition, the CIRM expects that the grants management system firm will comply with current industry standards and will maintain appropriate expertise at the firm's own expense. Proposer must have, at minimum, the following qualifications and experience:

.

¹ Bidder to complete as part of the proposal

- 1. Firm must be a professional grants application and management systems firm.
- 2. Firm must have sufficient staff to provide grants management application and system support to the CIRM to meet the deadlines outlined in Section A, Item 2, Scope of Services.
- 3. Independent Consultant Insurance Requirements
 - a. General Liability
 - i. Comprehensive or Commercial Form (minimum limits)

1.	Each Occurrence	\$1,000,000.00
2.	Products/Completed Operations Aggregate	\$1,000,000.00
3.	Personal and Advertising Injury	\$1,000,000.00
4.	General Aggregate*	\$1,000,000.00
	*Not applicable to comprehensive form	

*Not applicable to comprehensive form.

If the above insurance is written on a claims-made form, it shall continue for three years following termination of the agreement. The insurance shall provide for a retroactive date of placement prior to or coinciding with the effective date of the agreement.

- b. Business Automobile Liability (minimum limits): For owned, scheduled, non-owned, or hired automobiles with a combined single limit of not less than \$1,000,000 per occurrence.
- c. Workers' Compensation: as required under California State Law.
- d. Professional Liability Insurance (minimum limits):

i. Each Occurrence \$1,000,000ii. Project Aggregate \$2,000,000

e. Other insurance in amounts which from time to time may reasonably be required by the mutual consent of the CIRM and the Independent Consultant against other insurable hazards relating to performance.

C) Proposal Requirements and Information

1) Key Action Dates

It is recognized that time is of the essence. All Proposers are hereby advised of the following schedule and will be expected to adhere to the required dates and times:

<u>Date</u>	Action
May 25, 2007	RFP available to prospective firms
Week of June 4, 2007	CIRM will schedule a "bidder's conference," an in-person and call-in meeting where prospective

respondents can ask questions about and get clarifications of the RFP and RFP process.

June 22, 2007 Final Date for Proposal Submission.

Proposals must be received at the CIRM at 210 King Street, San Francisco, CA 94107 by

5:00 P.M. PST.

Week of June 25, 2007 CIRM may request bidders to do a presentation

on their system.

July 11, 2007 Proposed Award Date (Note: The actual award

date may be earlier.)

2) Firm's Experience and Staff

1. Detailed information regarding the grants application and management system, including prior relevant experience with grants management systems.

- i. <u>Qualifications and Experience of Firm</u> Discuss the overall experience of your firm that demonstrates your ability to successfully complete the Scope of Services and the criteria set in the Functional Requirements Document (Exhibit I).
- ii. <u>Qualification of Staff/Resumes</u> Identify and provide resumes of the staff that will be providing the services required by the proposal, including years and relevant experience for each person. Experience should include number of years at current firm as well as all prior service. Experience in grants application and management services should be detailed. The party in charge of the CIRM account must have at least five years prior experience with grants application and management systems.
- iii. The firm should insure that the quality and availability of its staff assigned to this agreement will be maintained over the term of the agreement. Any changes in assigned staff are at the discretion of the firm, provided that any replacements have substantially the same or better qualifications and experience than the original personnel.

3) References

Submit a list of at least three references (clients) to whom you have provided similar services within the past five years and contact names and telephone numbers for each. See Attachment 2.

4) Submission of Proposal

- a) Proposals should provide straightforward and concise descriptions of the Proposer's ability to satisfy the requirements of this RFP. The proposal must be complete and accurate. Omissions, inaccuracies or misstatements will be sufficient cause for rejection of a proposal.
- b) The proposal package should be prepared using plain 8½×11" paper, with one inch margins all around, using either Times Roman or Arial/Helvetica typefaces.

- c) All proposals must be submitted to the California Institute for Regenerative Medicine by the dates and times shown in Section C, Proposal Requirements and Information, Item 1) Key Action Dates. There is no exception for the acceptance of a late bid.
- d) One (1) original plus three (3) hard copies of the proposal must be submitted. In addition, the proposal must be submitted electronically, in PDF format, to the following email address: edorrington@cirm.ca.gov.
- e) The original proposal must be marked "ORIGINAL COPY". All documents contained in the original proposal package must have original signatures and must be signed by a person who is authorized to bind the proposing firm. All additional proposal sets may contain photocopies of the original package.
- f) The proposal envelope(s) should be addressed as follows and must be plainly marked with the RFP number and title:

Edward Dorrington
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107
Subject: Request for Proposal Grants Management System
RFP# CIRM 2060

If the proposal is made under a fictitious name or business title, the actual legal name of the proposer must be provided.

- g) All proposals shall include the documents identified in Section D, Required Attachments. Proposals not including all "required attachments" shall be deemed non-responsive. A non-responsive proposal is one that does not meet the basic proposal requirements.
- h) Mail or deliver proposals to the address as stated in 'f' above.
- Proposals must be submitted for the performance of all the services described herein.
 Any deviation from the work specifications will not be considered and will cause a proposal to be rejected.
- j) A proposal may be rejected if it is conditional or incomplete, or if it contains any alterations of form or other irregularities of any kind. CIRM may reject any or all proposals and may waive any immaterial deviation in a proposal. CIRM's waiver of immaterial deviation shall in no way modify the RFP document or excuse the proposer from full compliance with all requirements if awarded the agreement.
- k) Costs incurred for developing proposals and in anticipation of award of the agreement are entirely the responsibility of the proposer and shall not be charged to the CIRM.
- 1) An individual who is authorized to bind the proposing firm contractually shall sign the Attachment 3, Proposer Certification Form. The signature must indicate the title

- or position that the individual holds in the firm. An unsigned proposal may be rejected.
- m) A Proposer may modify a proposal after its submission by withdrawing its original proposal and resubmitting a new proposal prior to the proposal submission deadline as set forth in Section C, Proposal Requirements and Information, Item 1) Key Action Dates. Proposal modifications offered in any other manner, oral or written, will not be considered.
- n) A Proposer may withdraw its proposal by submitting a written withdrawal request to CIRM, signed by the Proposer or an authorized agent, addressed in accordance with 'f' above. A Proposer may thereafter submit a new proposal prior to the proposal submission deadline. Proposals may not be withdrawn without cause subsequent to proposal submission deadline.
- o) The CIRM may modify the RFP prior to the date fixed for submission of proposals by the issuance of an addendum to all parties who received a proposal package.
- p) The CIRM reserves the right to reject all proposals. The CIRM is not required to award an agreement.
- q) Before submitting a response to this solicitation, Proposers should review, correct all errors and confirm compliance with the RFP requirements.
- r) Where applicable, Proposer should carefully examine work sites and specifications in the Functional Requirements Document (Exhibit I). No additions or increases to the agreement amount will be made due to a lack of careful examination of work sites and specifications.
- s) More than one proposal from an individual, firm, partnership, corporation or association under the same or different names, will not be considered.
- t) CIRM does not accept alternate contract language from a prospective Consultant. A proposal with such language will be considered a counter proposal and will be rejected. The CIRM's terms and conditions are not negotiable.
- u) No oral understanding or agreement shall be binding on either party.

5) Evaluation Process

- a) At the time of proposal opening, each proposal will be checked for the presence or absence of required information in conformance with the submission requirements of this RFP.
- b) Proposals that contain false or misleading statements, or which provide references that do not support an attribute or condition claimed by the proposer, may be rejected.
- c) Award, if made, will be to the highest scoring responsible proposal. If a tie occurs the most competitive cost proposal will be the determining factor.

d) Proposal Evaluation

The CIRM desires a grants application and management system firm that demonstrates a high degree of experience, training and proficiency in the conduct of the various functions required by this RFP. The grants application and management firm should have extensive experience in the management of large grant funding systems.

The proposals that meet the Minimum Qualifications in Section B and the Proposal Requirements and Information in Section C will be evaluated and scored according to the criteria indicated below. The selection will be made by an evaluation committee of the CIRM. The following weighted factors (maximum points available for each criterion is noted) will be used by the evaluation committee to determine which proposal would provide the best value to CIRM using the requirements of this RFP.

(1) Qualification of Personnel

(20 points)

The CIRM will evaluate the individuals to be assigned to the contract on the basis of background and experience in related work.

(2) Experience as a Firm

(20 points)

The CIRM will evaluate the firm on the basis of the firm's overall experience demonstrating its ability to successfully complete the requirements identified in 1) Introduction and 2) Scope of Services, Section A.

(3) Responsiveness to the Scope of Work

(20 points)

The CIRM will evaluate the firm on the basis of the firm's overall understanding and description of the Scope of Work.

(4) Cost

(20 points)

The CIRM will score the cost upon the competitive cost proposal, Scope of Services, Section A, Item 2 C.

(5) Timing

(20 points)

The CIRM will score the proposal's timing based on the proposed timeline, as it relates to the timeline given in Section A.2.e.

Maximum Total Possible Points

100 points

6) Disposition of Proposals

- a) Upon proposal opening, all documents submitted in response to this RFP will become the property of the CIRM, and will be regarded as public records under the California Public Records Act (Government Code Section 6250 et seq.) and subject to review by the public.
- b) Proposal packages may be returned only at the Proposer's expense, unless such expense is waived by the CIRM.

7) Agreement Execution and Performance

- a) Service shall start on the express date set by the CIRM and the Consultant, after all approvals have been obtained and the agreement is fully executed. Should the Consultant fail to commence work at the agreed upon time, the CIRM, upon five (5) days written notice to the Consultant, reserves the right to terminate the agreement. In addition, the Consultant shall be liable to CIRM for the difference between Consultant's Proposal price and the actual cost of performing work by another Consultant.
- b) All performance under the agreement shall be completed on or before the termination date of the agreement.

D) Required Attachments

For your proposal to be considered responsive, all required attachments must be included with the RFP by the dates and times shown in Section C, Proposal Requirements and Information, Item 1, Key Action Dates.

Attachment 1- Required Attachment Checklist

Attachment 2-Proposer References

Attachment 3- Proposer Certification

Attachment 4- Payee Data Record (STD 204)

Attachment 5-Technical Proposal

E) Exhibits

- 1. Functional Requirements Document
- 2. Sample Independent Consultant Agreement

REQUIRED ATTACHMENT CHECK LIST

A complete proposal or proposal package will consist of the items identified below. Complete this checklist to confirm the items in your proposal. Place a check mark or "X" next to each item that you are submitting to the State. For your proposal to be responsive, all required attachments must be returned. This checklist should be returned with your proposal package also.

<u>Attachment</u>	Attachment Name/Description
 Attachment 1	Required Attachment Check List
 Attachment 2	Proposer References
 Attachment 3	Proposal/Proposer Certification Sheet
 Attachment 4	Payee Data Record (STD 204) (if currently not on file)
 Attachment 5	Technical Proposal

PROPOSER REFERENCES

Submission of this attachment is mandatory. Failure to complete and return this attachment with your bid may cause your bid to be rejected and deemed non-responsive.

List below three references for services performed within the last five years, which are similar to the scope of work to be performed in this contract.

REFERENCE 1			
Name of Firm			
Street Address	City	State	Zip Code
Contact Person		Telephone Number	
Dates of Service		Value or Cost of Service	

Brief Description of Service Provided

REFERENCE 2					
Name of Firm Street Address	City	State	Zip Code		
Contact Person		Telephone Number			
Dates of Service		Value or Cost of Service	ee		

Brief Description of Service Provided

REFERENCE 3			
Name of Firm Street Address	City	State	Zip Code
Contact Person	•	Telephone Number	•
Dates of Service		Value or Cost of Servi	ce

Brief Description of Service Provided

PROPOSAL/PROPOSER CERTIFICATION SHEET

This Proposal/Proposer Certification Sheet must be signed and returned along with all the "required attachments" as an entire package in duplicate with <u>original signatures</u>. The proposal must be transmitted in a sealed envelope in accordance with RFP instructions.

For RFP Primary Only:

- A. Our all-inclusive cost proposal is submitted in a sealed envelope marked "Cost Proposal Do Not Open".
- B. Place all required attachments behind this certification sheet.
- C. I have read and understand the DVBE Participation requirements and have included documentation demonstrating that I have met the participation goals or have made a good faith effort.
- D. The signature affixed hereon and dated certifies compliance with all the requirements of this proposal document. The signature below authorizes the verification of this certification.

An Unsigned Proposal/Proposer Certification Sheet May Be Cause For Rejection

1. Company Name	2. Teleph	one Number	2a. Fax Number
	()		()
3. Address			
Indicate your organization type: 4. ☐ Sole Proprietorship 5.	☐ Partner	ship	6. Corporation
Indicate the applicable employee and/or corporation nu 7. Federal Employee ID No. (FEIN)	mber:	8. California Corpo	oration No
		o. camorna corpe	, a.i.o., 1101
Indicate applicable license and/or certification inform	nation:		
10. Proposer's Name (Print)		11. Title	
10. I Toposer's Name (Finit)		TT. THE	
12. Signature		13. Date	
12. digitataro		To. Date	
14 Are you cartified with the Department of Canaral C	omicoo Offi	on of Cmall Dunings	Cortification and
14. Are you certified with the Department of General S Resources (OSBCR) as:	ervices, Om	ce of Small Business	s Certification and
a. California Small Business Enterprise		ed Veteran Business	
Yes No l	If yes,	enter your service co	de below:
If yes, enter certification number:	ı		
NOTE: A server of view Contification is no serious to be	. :		to an in the short (Wan)
NOTE : A copy of your Certification is required to be			ems is checked "Yes".
Date application was submitted to OSBCR, if an ap	plication is p	pending:	

Completion Instructions for Proposal/Proposer Certification Sheet

Complete the numbered items on the Proposal/Proposer Certification Sheet by following the instructions below.

Item Numbers	Instructions			
1, 2, 2a, 3	Must be completed. These items are self-explanatory.			
4	Check if your firm is a sole proprietorship. A sole proprietorship is a form of business in which one person owns all the assets of the business in contrast to a partnership and corporation. The sole proprietor is solely liable for all the debts of the business.			
5	Check if your firm is a partnership. A partnership is a voluntary agreement between two or more competent persons to place their money, effects, labor, and skill, or some or all of them in lawful commerce or business, with the understanding that there shall be a proportional sharing of the profits and losses between them. An association of two or more persons to carry on, as co-owners, a business for profit.			
6	Check if your firm is a corporation. A corporation is an artificial person or legal entity created by or under the authority of the laws of a state or nation, composed, in some rare instances, of a single person and his successors, being the incumbents of a particular office, but ordinarily consisting of an association of numerous individuals.			
7	Enter your federal employee tax identification number.			
8	Enter your corporation number assigned by the California Secretary of State's Office. This information is used for checking if a corporation is in good standing and qualified to conduct business in California.			
9	Complete, if applicable, by indicating the type of license and/or certification that your firm possesses and that is required for the type of services being procured.			
10,11 12, 13,	Must be completed. These items are self-explanatory.			
14	If certified as a California Small Business, place a check in the "yes" box, and enter your certification number on the line. If certified as a Disabled Veterans Business Enterprise, place a check in the "Yes" box and enter your service code on the line. If you are not certified to one or both, place a check in the "No" box. If your certification is pending, enter the date your application was submitted to OSBCR.			

Payee Data Record (STD 204)

STATE OF CALIFORNIA-DEPARTMENT OF FINANCE
PAYEE DATA RECORD
(Required when receiving payment from the State of California in lieu of IRS W-9)
STD. 204 (Rev. 6-2003)

2	INSTRUCTIONS: Complete all information on this form. Sign, the bottom of this page. Prompt return of this fully completed it his form will be used by State agencies to prepare Information F Statement. NOTE: Governmental entities, federal, State, and local (includin PAYEE'S LEGAL BUSINESS NAME (Type or Print) SOLE PROPRIETOR – ENTER NAME AS SHOWN ON SSN (L.)	form will prevent delays when pro Returns (1099). See reverse side ng school districts), are not require	cessing payments. Info for more information a ed to submit this form.	rmation provided in	
	,				
	MAILING ADDRESS	BUSINESS ADDRESS			
	CITY, STATE, ZIP CODE	CITY, STATE, ZIP CODE			
BAYEE ENTITY TYPE ENTER FEDERAL EMPLOYER IDENTIFICATION NUMBER (FEIN): CORPORATION: MEDICAL (e.g., dentistry, psychotherapy, chiropractic, etc.) LEGAL (e.g., attorney services) EXEMPT (nonprofit) ALL OTHERS				NOTE: Payment will not be processed without an accompanying taxpayer I.D. number.	
ONE BOX ONLY	IE BOX INDIVIDUAL OR SOLE PROPRIETOR				
PAYEE RESIDENCY STATUS	California resident - Qualified to do business in California or maintains a permanent place of business in California. California nonresident (see reverse side) - Payments to nonresidents for services may be subject to State income tax withholding. No services performed in California. Copy of Franchise Tax Board waiver of State withholding attached.				
5	I hereby certify under penalty of perjury that the Should my residency status change			and correct.	
	AUTHORIZED PAYEE REPRESENTATIVE'S NAME (Type or R	Print)	TITLE		
	SIGNATURE	DATE	TELEPHONE		
	Please return completed form to: Department/Office: State Controller's Office				
6	-	_			
	Unit/Section:Contracts Unit				
	Mailing Address: 300 Capitol Mall, Suite 62	22			
	City/State/Zip: Sacramento, CA 95814				
	Telephone: (916) $322-0527$ Fax: (916) $327-1259$				
	E-mail Address: pmoore@sco.ca.gov			_	

Technical Proposal

(attach your detailed response to the RFP here)

EXHIBIT 1

CIRM Grants Management System Functional Requirements Document

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INTRODUCTION

The California Institute for Regenerative Medicine (CIRM) was established in early 2005 with the passage of Proposition 71, the California Stem Cell Research and Cures Initiative. The statewide ballot measure, which provided \$3 billion in funding for stem cell research at California universities and research institutions, was approved by California voters on November 2, 2004, and called for the establishment of a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities.

The Independent Citizens Oversight Committee ("ICOC") is CIRM's 29-member governing board. The ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non-profit academic and research institutions, patient advocacy groups and the biotechnology industry. With respect to the grant-making process and the grant management system, the ICOC makes the final choice of award for each grant application in every program.

In support of CIRM's mission, it is critical that a comprehensive Grant Application and Management System ("the system") be implemented to allow CIRM to manage and track its grant-making activities.

Purpose

The purpose of this Functional Requirements Document is to outline CIRM's need for a grants management system, the functionality required of the system, the constraints under which the system is to be implemented, and the technical requirements for its implementation.

Scope

This document encompasses the functional and design requirements for CIRM's Grant Application and Management System, which will include the elements necessary for a completely electronic system.

Background

As described above, CIRM's mission is to provide grants and loans to both non-profit and for-profit California entities, for the purposes of conducting stem cell research, creating research facilities to enable stem cell research, and other related activities. Within the organization, the Science Office has responsibility for the grant-making and grant management tasks. Under the direction of the Director of Scientific Activities, the Grant Management Officers (GMO) and Science Officers (SO) will be the staff members responsible for working with the system. The duties of these officers as they relate to the system will be described below.

The Director of Grants Management Systems (DGMS) will be responsible for leading the project to create the grant management system.

Constraints

There are several technical constraints to which a successful grant management system will be bound. They are:

- All non-staff elements of the system (including, but not limited to, Letter Of Intent (LOI) submission, application submission, application review, and progress report submission) must be web-based.
- Access to the web-based portions of the system must be fully functional across all major operating systems (Windows XP, Windows Vista, Mac OS X, Linux) and all major web browsers (Internet Explorer version 5.5 or higher, Mozilla version 1.0 or higher, Firefox version 1.0 or higher, and Safari version 1.0 or higher)
- The system must conform to Section 508 accessibility standards (as mandated by California Government Code Section 11135 (d) (2)).

Multiple Systems

While respondents will ideally propose a single system to handle all of the requirements outlined below, it is understood that integrating multiple systems may be required to meet all of CIRM's functionality needs. Therefore, we will allow responses that propose integrating several systems, as long as the following conditions are met:

- The set of systems proposed, along with any integration code, comprise a complete system which is responsive to all of the requirements outlined in this RFP.
- The business is experienced in and committed to the Grants management and administration software sector.
- The respondent demonstrates a strong working relationship with all 3rd-party vendors whose systems are proposed.
- The respondent documents that they have integrated similar systems in past projects.
- The respondent will act as a single point of contact for all implementation, licensing, maintenance, help desk, and troubleshooting of the proposed system.

Document Overview

The rest of this document consists of 3 major sections: Methodology, Functional Requirements, and Other Requirements.

The Methodology section outlines the methodology used to determine the functional requirements for the system.

The Functional Requirements section is the bulk of the document, and specifies in detail the minimal functionality required by the system. The requirements take three forms:

- "Must have" or "Will" items. Functionality described using terms like "the system must..." or "the system will..." are absolute requirements, and no response to the RFP will be considered valid unless it addresses each of these items.
- "Should have" items. Functionality that is described using terms like "the system should..." are items that, while not absolutely necessary, make a substantive difference in the overall functioning of the system, and both their presence in and the depth to which they are addressed in the response to the RFP will have an impact on the award of the implementation.
- "May have" items. Functionality that is described using terms like "the system may..." describe functionality that is "nice to have." They are neither requirements nor are they major areas of functionality, but they are the type of items that provide polish to a system, and as such do contribute to its overall success.

Finally, the Other Requirements section details the requirements of the system that are not functionality-related. These include such requirements as data integrity, low-level security, system availability, etc.

References

The following set of documents will be helpful in understanding CIRM's mission, and the constraints and policies to which it, and its grantees, are bound:

CIRM Web Site http://www.cirm.ca.gov/

CIRM GAP http://www.cirm.ca.gov/policies/pdf/CIRMPolicyStatement.pdf

(Grants Administration Policy)

CIRM policies http://www.cirm.ca.gov/policies/

Proposition 71 http://www.cirm.ca.gov/prop71/pdf/prop71.pdf

METHODOLOGY

There were two approaches used to determine the functional requirements of the system. The first was a series of interviews. The interviews were both internal and external. Internally, the Director of Scientific Activities, who is ultimately responsible for the management of the grant-making process, was the primary, and invaluable, source of information on CIRM's requirements. Externally, we interviewed a number of people in positions of authority at a variety of grant-making organizations, both governmental and private foundations. The interview process was valuable not only to provide a wide overview of how grant application and management systems might work in an organization, but also because CIRM was such a young agency, there were not a lot of "legacy" processes and procedures to mine for requirements.

However, despite CIRM's young age, there have been several grants programs launched, and so the second approach to identifying the functional requirements of the system was through direct experience. As CIRM, and specifically the Science Office, went through the process of creating and running several grant-making programs, the requirements for the grants system gelled.

FUNCTIONAL REQUIREMENTS

Workflow

Once a Request For Applications (RFA) has been announced and posted to our web site, potential applicants can log in to the system and submit an LOI. At this point they are assigned an application number, which is used as an identifier both in the system and through external communications.

Once assigned an application number, the applicant fills in and submits an application. After the deadline for applications has passed, CIRM staff will assign each application to several reviewers.

The reviewers will then log in to the system, fill and submit their preliminary reviews for each of the applications assigned to them. At a specified later date, there are one or more review meetings, where the reviewers come together to discuss the applications and give a final score to each application. The end result of the meeting is that each application will be placed into one of three categories: 1. Recommended for funding, 2. Recommended should funds become available, and 3. Not recommended for funding at this time.

After the review meeting(s), the ICOC meets to consider the recommendations from the reviewers, and make their final decision for award.

Grant applicants who have been awarded grants are vetted to ensure that their information, including budget information, is complete and accurate, and that all necessary certifications, assurances, and any other paperwork required has been submitted. They are then sent a Notice of Grant Award (NGA) letter, informing them of the award. The grantee must sign and return the NGA. At this point, the grant enters the grant management cycle.

The grant management cycle entails making any required adjustments to the amount of the award, and once all of the requirements for the award are met, making the first payment on the award. At a given later date, the grantee is required to submit one or more progress reports. Based on those reports, further adjustments might be made, and the cycle continues until the period of the grant is over. At that point, the grant is closed out of the system.

User Requirements

The following table lists the various classes of users of the system, along with a list of which functional requirements they will need access to in order to perform their duties.

User Type	Role Name	Functional Requirements
Administrative	Administrator	3.1-3.8, 3.9, 3.10.1, 3.10.4, 3.10.10, 3.11.1, 3.11.3, 3.12.3, 6, 7
" "	GMO	4, 5.6, 6
" "	GPO	4.1, 4.5, 4.6, 4.12.1, 5.6, 6
Review	Scientific Reviewer	3.10.1, 3.10.4, 3.10.6-10
" "	Scientific Specialist	3.11.3, 3.11.5-6
" "	Patient Advocate	3.12
" "	ICOC Member	3.13
Applicant/Grantee	Applicant	2
" "	Grantee	5

Workflow Diagram

The following diagram outlines the basic workflow in the system.

Application / Review / Approval

Grants Management / Progress Reporting

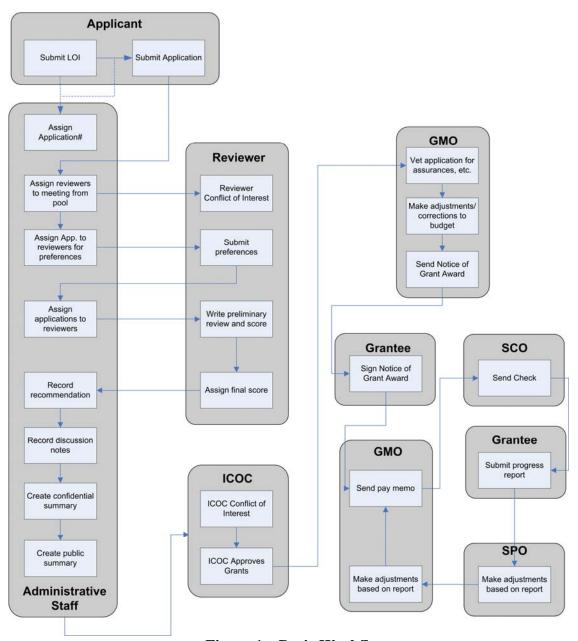


Figure 1 – Basic Workflow

Functional Requirements

The functional requirements of the system can be broken down into the overall requirements for the system as a whole, and the requirements for each of the 6 functional areas, Application, Review, Grants Management, Progress Reporting, Reporting, and Administration.

FR1: System-wide Functional Requirements

Section/ Requirement ID	Requirement Definition	Requirement
FR1.1	Workflow/task-based interface	Must
FR1.1.1	Support workflow "guards" or required checks	Must
FR1.1.2	Rule-based triggers	Must
FR1.1.3	Administrative override of workflow	Must
FR1.2	Access to functionality based on dates for applicants and reviewers	Must
FR1.3	Administrative ability to override date-based restrictions	Should
FR1.4	Full-text search	Should
FR1.5	Correctly identify users and institutions	Must
FR1.6	Data export capability	Should
FR1.7	Critical data change logging	Should
FR1.8	User-specific "home page"	Must/Should

- FR1.1 <u>Workflow/task-based interface</u>. Given the anticipation of a large number of ongoing grant programs, and the limited size of both CIRM's applicant pool and especially its reviewers, the system must support a task-based workflow, where users of the system are automatically presented with a prioritized list of tasks they need to accomplish. This will enable users of the system to be productive without getting "lost" in the interface.
- FR1.1.1 <u>Support workflow "guards" or required checks</u>. Because CIRM is legally required to ensure that certain requirements have been met before a grant can be paid, it is important that there be a mechanism whereby the system provides a means for staff members to certify that those requirements have been met. The set of possible requirements will vary by RFA, and each grant application will have its own specific subset of those requirements which apply. Therefore the system must provide at a minimum a means to define a set of requirements that must be met before a grant can get paid, on a per-RFA basis. Ideally the system should provide a means to attach such conditions to any step within the workflow.
- FR1.1.2 <u>Rule-based triggers</u>. Due to the sensitive and complex nature of the grants that CIRM gives, there can be a number of complex inter-dependencies between the various requirements associated with a grant, as well as information provided by grantees in either their applications or their progress reports. The system must provide a means by which a set of rule-based triggers can be defined, which have associated actions which fire when the conditions of the rule are met. As an example, a grant application form may ask an applicant if they utilize a certain process in their work. If they check "Yes", then the rule system would trigger an action that would send an email to a CIRM staff person, notifying them of that fact. This would alert the staff member that they need to follow up with the applicant, or perform some other relevant actions.

- FR1.1.3 <u>Administrative override of workflow</u>. As there will inevitably be occasions where a fixed workflow will be too restrictive, the system must provide the ability for properly authorized administrative users to move a particular application or grant further along the workflow, overriding the system.
- FR1.2 Access to functionality based on dates for applicants and reviewers. Given the above requirement, and that many user tasks are only valid for certain dates, the system must allow/restrict access to various functions based on a start-date/end-date range. For example, applicants must not be allowed to start applying for a particular grant program before the appropriate time, and must not be allowed to submit an application once its due date has passed. Similarly, reviewers must not, in general, be allowed to submit their review of a particular application after its due date.
- FR1.3 <u>Administrative ability to override date-based restrictions</u>. Although it is important that no user be able to perform a particular task outside of the specified date range, it is also important that the system allow administrative users to override such restrictions on an as-needed basis. Therefore the system should allow administrators to allow exceptions to the date-based availability of tasks. The system should allow administrators to do this on a fine-grained (i.e. per-user or per-grant or per-cycle) basis.
- FR1.4 <u>Full-text search</u>. The system should support the ability to do a full-text search across both data stored in database fields, as well as in documents attached to items in the system (i.e. PDF files, Microsoft Word and Excel files, etc).
- FR1.5 <u>Correctly identify users and institutions</u>. In order to minimize duplicated records, and to make reporting on institutional and individual progress, the system must provide mechanisms to ensure that data entered for a particular contact or institution uniquely identifies the contact or institution. This mechanism must extend throughout grant applications, progress reports, etc. For example, if a particular grant application form includes fields to specify collaborators, and an applicant enters data on a particular person, "Joe Smith", the system must provide the ability to verify that this person is the same "Joe Smith" that was identified previously, say in a different grant or application, and if so, tie the persons records together.
- FR1.6 <u>Data export capability</u>. The system should provide a simple, convenient means by which staff members can export a variety of data related to the grants. This data should be made available in a variety of formats, with an Excel spreadsheet (or comma-separated-value file) as a minimum format.
- FR1.7 <u>Critical data change logging</u>. It is important for both auditing purposes, and for error-correction, that the system record who made changes to important data within the system. The system should at least log changes to user authorization, grant budget data, and the state of checklist requirements (see FR1.1.1). Ideally the system should provide a means to select which data changes get logged.
- FR1.8 <u>User-specific</u> "home page". In order to streamline the activities of users of the system, the system must provide a user-specific "overview" page/section, where staff can see at a glance the state of their responsibilities and tasks. The system should provide a similar overview for clients (i.e. grantees, applicants, and reviewers) of the system.

FR2: Application Functional Requirements

Section/ Requirement ID	Requirement Definition	Requirement
FR2.1	Programs/RFAs	Must
FR2.1.1	RFA-specific tagging	Must
FR2.2	Unassisted user registration	Must
FR2.3	Letter of Intent	Must
FR2.3.1	Eligibility validation	May
FR2.4	Application templates	Must
FR2.5	Arbitrary attachments	Should

Section/ Requirement ID	Requirement Definition	Requirement
FR2.5.1	Number of attachments limited	Should
FR2.5.2	Broad set of attachment types	Must/Should
FR2.5.3	Type of attachments limited	Should
FR2.5.4	Size of attachments limited	Must
FR2.6	Paged interface	Must
FR2.6.1	Arbitrary number of sub-items	Must
FR2.7	Broad set of field types	Must
FR2.7.1	Field validation	Must
FR2.7.2	Field grouping	Must
FR2.8	Complex budget	Must
FR2.8.1	Application-level budget	Must
FR2.8.2	Sub-item-level budget	Must
FR2.8.3	Budget grouping	Must
FR2.8.4	Calculated summary/roll-up fields	Must
FR2.9	Completed application available as PDF	Should/May
FR2.9.1	PDF includes all attached files	Should
FR2.9.2	Ability to create PDFs with only a subset of fields	Should
FR2.10	Keep unsuccessful application data	Must

- FR2.1 <u>Programs/RFAs</u>. New applications are tied to a specific RFA, or program. Each RFA consists of a set of data including a name, a set of valid dates for various activities (see FR1.2), etc. Therefore, the system must support the notion of a "program" or RFA as a distinct data object.
- FR2.1.1 <u>RFA-specific tagging</u>. Each RFA must be able to be tied to one or more specific aims within CIRM's scientific strategic plan. This can be accomplished by allowing RFAs to be given multiple tags. Therefore, the system must be able to tag individual RFAs. The set of tags can either be pre-defined or user-entered.
- FR2.2 <u>Unassisted user registration</u>. CIRM does not use an invitation model for its grants programs, so therefore the list of applicants to a particular RFA is not known beforehand. Therefore the system must allow new applicants to register and become authenticated users. This process must not require administrative involvement. In addition, in order to limit the amount of duplicated users, the system should make every effort to determine if a user attempting to register is already listed in the system.
- FR2.3 <u>Letter of Intent</u>. In order to help CIRM ascertain how many applications it will receive in response to a given RFA, the system must allow interested potential applicants to submit a Letter of Intent (LOI) for an open RFA. The LOI form must allow for the gathering of an arbitrary, though usually very small, amount of data to help CIRM in allocating reviewers, amongst other needs. The LOI form must be customizable on an RFA by RFA basis.
- FR2.3.1 <u>Eligibility validation</u>. The system may allow administrators to determine that a particular submitted LOI is ineligible, and thus block the applicant from beginning/ submitting an application. This validation will not be automated, as the criteria used for judging eligibility are variable and difficult to automate.

- FR2.4 <u>Application templates</u>. In designing a new application form, often the new form will be very similar to a prior form. Therefore, to save significant time, the system must allow new forms to be based on old forms, or templates.
- FR2.5 <u>Arbitrary attachments</u>. Often the response to a particular RFA will require the applicant to provide data in a format which is impossible to deliver in a web-based form field. This data might include floor plans and drawings, spreadsheets, scanned letters of collaboration, etc. Therefore the system should allow applicants to attach other files to their application.
- FR2.5.1 <u>Number of attachments limited</u>. The system should allow administrators to set an upper limit on the number of files attached to an application, and this limit must be settable on a per-RFA basis.
- FR2.5.2 <u>Broad set of attachment types</u>. CIRM cannot know in advance what types of files will be needed, therefore the system should support as broad an array of file types as possible. At a minimum, the system must support the attachment of Microsoft Word, Microsoft Excel, PDF, and JPEG files.
- FR2.5.3 <u>Type of attachments limited</u>. Although it is important to support a wide array of file types, the system should allow administrators to limit the types available on a per-RFA basis.
- FR2.5.4 <u>Size of attachments limited</u>. It is very important to allow administrators to limit the size of attachments, to prevent both accidental and deliberate system instability. Therefore the system must allow administrators to limit the size of attachments allowed on a per-RFA basis. The system may allow administrators to limit attachment-size on a per-document type basis as well.
- FR2.6 <u>Paged interface</u>. Given CIRM's experience so far, and the fact that many more complex grant programs are expected, it is anticipated that the application forms will be extremely large and complex. It is essential that the process of filling out an application be as simple as possible. Therefore the system must use a "paged" interface, where the application is broken into a number of sub-pages. The system may also allow a "tree-based" navigation system, where sub-pages can have further sub-pages, etc.
- FR2.6.1 <u>Arbitrary number of sub-items</u>. An application doesn't consist of a simple flat collection of data fields. Rather an application will consist of numerous entities, each of which themselves may consist of other entities, until finally an entity consists of nothing but "primitive" fields. An example of this is that an application may include a list of personnel who will be associated with the grant. Each personnel record itself might consist of several complex entities, such as a collection of demographic data, budget data, etc. Therefore the system must allow application data to be partitioned into an arbitrary number of sub-items, and each sub-item similarly must be able to contain both fields and other sub-items.
- FR2.7 <u>Broad set of field types</u>. In order to enhance user experience and minimize data entry errors, it is important that the system support a variety of field types. While it is true that any data type can be encoded in a text area field, certain field types are more appropriate for particular data. The system must support at least the following field types:
 - Radio button groups.
 - Checkboxes.
 - Checkbox groups.
 - Single date and start-date/end-date range.
 - Single line text field.
 - Single line numeric field (generally dollars or percentages).
 - Text area.
 - Drop-down with database-backing for options.
 - Multi-select list box with database-backing for options.

- FR2.7.1 Fields must allow a variety of validation. In order to enhance the user's experience, and to minimize the necessity of post-submission intervention on the part of CIRM staff, application fields must allow for validation. The system should support as wide a variety of validation types as possible, but at a minimum it must support length validation for text fields, and minimum/maximum validation for numeric fields. The system should also support minimum/maximum # of items checked for checkbox groups, and minimum/maximum amounts for calculated fields.
- FR2.7.2 <u>Fields must be able to be grouped</u>. As mentioned above (FR2.6.1), applications will consist of numerous sub-items. From a user interface standpoint, those sub-items must be distinguished on a particular page via grouping. Also, the system must allow arbitrary grouping of related fields, even if those fields do not themselves constitute a proper sub-item.
- FR2.8 <u>Must support complex budgeting</u>. Many of the grant programs CIRM will be funding will have very complex budget requirements, and will require applicants and grantees to provide significantly detailed budget data. The system must support this, and make entering this data as simple and efficient as possible. Most grant programs will be several years long, and generally each budget line item will be repeated for each year, to allow applicants to express known or projected cost changes. In addition, as noted below (FR2.8.4), in order to help applicants keep track of and validate the budget data they're entering, the system must support read-only calculated data fields within the budget section. Figure 2 (below) shows an example of the type of budget data required (calculated fields have a green background).

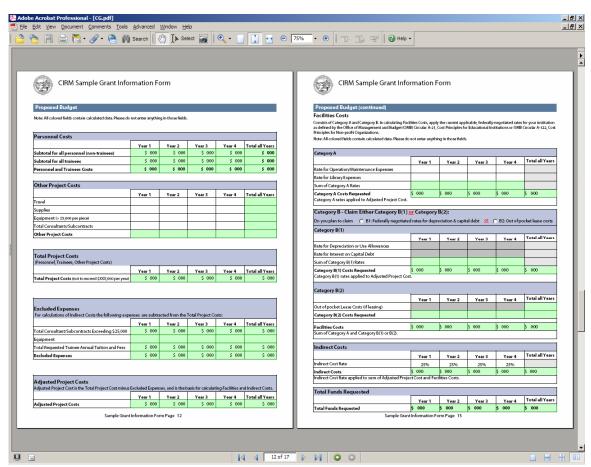


Figure 2 – Sample Budget Data Pages

FR2.8.1 <u>Application-level budget</u>. Detailed budget data will be required for the application as a whole. The budget pages in Figure 2 (above) are examples of application-level budget data.

FR2.8.2 <u>Sub-item-level budget</u>. In addition to gathering data for the application in its entirety, several sub-items may also require separate budget detail, which will then be rolled up in the application-level budget. An example of this is that CIRM requires personnel budget data on an individual basis. Figure 3 shows an example of a single person's budget record. This data might be repeated for each individual in the application. Therefore the system must support sub-item (or hierarchical) budget fields.

'his Key Individual's Budget					
	Year 1	Year 2	Year 3	Year 4	Total
Percent Effort					
Annual Base Salary					
Requested Salary*	\$ 000	\$ 000	\$ 000	\$ 000	\$ 000
Annual Fringe Benefit Rate					
Annual Fringe Benefit	\$ 000	\$ 000	\$ 000	\$ 000	\$ 000
Requested Annual Fringe Benefit*	\$ 000	\$ 000	\$ 000	\$ 000	\$ 000
Subtotal	\$ 000	\$ 000	\$ 000	\$ 000	\$ 000
*Note: Requested rates are based on percent effort. All colored fields contain calculated data. Please do not enter				ot enter anything	in those fields.

Figure - Sample Personnel Budget Section

- FR2.8.3 <u>Budget grouping</u>. An extension of the field groups (FR2.7.2), the system must support the grouping of budget fields into related entities. In Figure , the groups "Personnel Costs" and "Other Project Costs" are examples.
- FR2.8.4 <u>Calculated summary/roll-up fields</u>. Generally (though not exclusively) to be used within the budget area, these would be display-only data that is calculated based on the values of other fields. The system must allow the display of calculated data, automatically updated as the values in the source fields' changes.
- FR2.9 <u>Completed application available as PDF</u>. Once the application is finished, the system must make the completed application data available in full as a PDF file. The file should generally mimic the page structure of the application, although the system may allow the structure of the generated PDF to be altered.
- FR2.9.1 <u>PDF</u> includes all attached files. The system should have the ability to include all of the attached files as part of the generated PDF file. Therefore, the system should be able to render any file type that it supports into PDF format.
- FR2.9.2 <u>Ability to create PDFs with only a subset of fields</u>. Because it may happen that CIRM would like to allow certain groups access to view only a subset of the fields that make up a given application, the system should allow the generation of additional PDF files for each application, which contain only certain subsets of the application data. The system should provide an administrative interface for choosing the fields to display, and that choice should be on a per-RFA basis.
- FR2.10 <u>Keep unsuccessful application data</u>. Once grant applications for a particular RFA have been approved, and move on to become active grants in the system, the system must keep the data on applications which were not approved for funding. This data must be able to be queried through the reporting system.

FR3: Application Review Functional Requirements

Section/ Requirement ID	Requirement Definition	Requirement
FR3.1	Multiple reviewer groups	Must
FR3.2	Multiple review meetings per RFA	Must

Section/ Requirement ID	Requirement Definition	Requirement
FR3.3	Multiple RFAs per review meeting	Must
FR3.4	Arbitrary set of reviewer pre-meeting tasks	Must
FR3.5	Reviewers from multiple reviewer groups assigned to an RFA	Must
FR3.6	Reviewers from multiple reviewer groups assigned to a meeting	Must
FR3.7	RFA & reviewer group-specific functionality	Must
FR3.7.1	Review criteria	Must
FR3.8	Staff-side review summary interface	Must
FR3.8.1	Confidential summary	Must
FR3.8.2	Public summary	Must
FR3.9	Reviewer participation tracking	Should
FR3.10	Scientific review group	
FR3.10.1	Assignment of members to an RFA review	Must
FR3.10.2	Reviewer-led conflict of interest assessment	Must
FR3.10.3	Reviewer expertise/preference assessment	Must
FR3.10.4	Many-to-many assignment of applications to reviewers	Must
FR3.10.5	Reviewer access to non-conflicting application data (PDFs)	Must
FR3.10.6	Preliminary review interface	Must/Should
FR3.10.7	Reviewer access to other reviewer comments	Must
FR3.10.8	Per-application notes	Should
FR3.10.9	Final review interface	Must/May
FR3.10.10	Staff-side Recommendation interface	May
FR3.11	Scientific specialist review group	
FR3.11.1	Assignment of members to an RFA review	Must
FR3.11.2	Specialist expertise/preference assessment	Must
FR3.11.3	Many-to-many assignment of applications to specialists	Must
FR3.11.4	Specialist access to assigned applications data (PDFs)	Must
FR3.11.5	Specialist review interface	Must
FR3.12	Patient Advocate review group	
FR3.12.1	Patient Advocate conflict of interest assessment	Must
FR3.12.2	Patient Advocate access to non-conflicting application data (PDFs)	Must
FR3.13	ICOC review group	
FR3.13.1	Conflict of interest assessment	Must
FR3.13.2	ICOC access to Public Summaries	Must
FR3.13.3	Per-application notes	May

Section/ Requirement ID	Requirement Definition	Requirement
FR3.13.4	Final funding decision	May
FR3.14	Other review groups	May

FR3 Review Requirements. CIRM has certain requirements for how the grant review process occurs. CIRM's reviewers in general just make recommendations, choosing between three different recommendations: 1. Recommended for funding; 2. Recommended should funds be available; and 3. Not recommended for funding at this time. The ICOC makes the final determination of which applications to fund. The basic workflow is as follows. Once the application period for a given RFA has ended, and administrative staff has vetted the applications to ensure that applicants are eligible, at least one review meeting is scheduled, along with a particular ICOC meeting to follow. Science Office staff assign reviewers to applications (see the individual functional requirements below for details). Once reviewers have been assigned applications, they will use the system to read the application and write their initial review, including a preliminary score from 1 to 100. At the review meeting, applications will be discussed and a final score given. Then the reviewers will determine to which of the 3 categories the application will be assigned. This set of recommendations is then taken to the appropriate ICOC meeting, where the members vote on the applications to determine their funding status.

- FR3.1 Multiple reviewer groups. Within the CIRM grants review system, reviewers are broken into a number of specialized categories, each of which will have different rights and responsibilities. The known groups are outlined in FR3.10 through FR3.13, though it is possible that there may be more groups defined later. Therefore the system must support the ability to define different groups of reviewers, each with unique rights and responsibilities. User records must not be tied to a particular group (i.e. a single user might be a member of one group for one RFA, and a different group for another). In addition, users may actually be members of two groups simultaneously in a single RFA (see the "Patient Advocate" and "ICOC" groups). Finally, a single group might have different rights and responsibilities within a single RFA, in different review meetings. The system may handle this by defining separate system-level groups for those users.
- FR3.2 <u>Multiple review meetings per RFA</u>. Given CIRM's structure, it is always the case that grant programs have at least two review meetings before the grants are awarded (at least one substantive review meeting, and the ICOC meeting wherein the ICOC reviewer group actually determines the grant awards). Therefore the system must support hosting multiple review meetings for every RFA.
- FR3.3 <u>Multiple RFAs per review meeting</u>. It is possible that CIRM may review multiple RFAs in a single meeting. Therefore, the system must support the ability of multiple RFAs to be assigned to a single meeting.
- FR3.4 <u>Arbitrary set of reviewer pre-meeting tasks</u>. Reviewers will often need to perform certain tasks, such as filling in various certification forms, reviewing guidelines, etc., prior to attending a meeting that they are assigned to. In addition to the tasks outlined below in the reviewer group-specific functional requirements, the system must support the ability to define an arbitrary set of tasks to be performed by the reviewer prior to a meeting. The system must associate these tasks to both reviewer group and meeting, and it should also associate them to a particular RFA, in the case where multiple RFAs will be reviewed in a given meeting.
- FR3.5 Reviewers from multiple reviewer groups assigned to an RFA. It is likely that for a given RFA, there will be several reviewer groups assigned to review the applications. For example, during a scientific review, members of both the scientific and the specialist review groups might be assigned to review the applications. Therefore the system must support the assignment of members of multiple review groups to a given RFA.
- FR3.6 <u>Reviewers from multiple reviewer groups assigned to a meeting</u>. Similarly to FR3.5, reviewers from multiple reviewer groups will often attend a given review meeting. Therefore the system must support the ability to assign members of multiple review groups to a given review meeting.
- FR3.7 <u>RFA & reviewer group-specific functionality</u>. The particular functionality that a reviewer needs to access when reviewing a given grant application will vary based on the reviewer group that the reviewer is

in, as well as the particular RFA that they are reviewing. The system must support having RFA and reviewer group-specific functionality within the review module.

- FR3.7.1 <u>Review criteria</u>. The primary functionality which will differ within the review module is the criteria by which the application is to be reviewed. Generally these criteria will consist of either text fields for the reviewer to fill in, or a numeric assignment, such as the score. The system must support multiple review criteria using these field types.
- FR3.8 <u>Staff-side review summary interface</u>. Once the non-ICOC review meetings for a given RFA have been completed, CIRM's administrative staff will need to generate two summaries of the reviews, based on the preliminary critiques entered by the review groups, notes taken by the reviewers during the review meeting(s), and staff-entered discussion notes. The disposition of these summaries varies as detailed below. The system must support functionality to enable staff members to generate these summaries.
- FR3.8.1 <u>Confidential summary</u>. A confidential summary is prepared, which includes the final score given to the application, the amount requested in the application, and a staff-written review which summarizes all of the preliminary reviews and the notes taken on the discussion of the application during the review meeting(s). The confidential summary must be made available only to the applicant.
- FR3.8.2 <u>Public summary</u>. Using the confidential summary as a base, the public summary is essentially a "lay" version of the confidential review, with all proprietary information and identifiers redacted. In addition, it contains the applicant-provided lay abstract and statement of benefit to California. The public summaries, once they are complete, must be made available for the public to view with no access restrictions. This functionality may be provided either as a set of unrestricted web pages hosted by the system, or the system may provide an interface to export these summaries for hosting on CIRM's main web site
- FR3.9 <u>Reviewer participation tracking</u>. As an aid to staff for determining which members of the working group to assign to review a particular RFA, the system should provide a means to query and report on the number of times each reviewer has participated in a review meeting and to record notes by administrative staff for each RFA.
- FR3.10 <u>Grants Review Working Group review group</u>. The Grants Review Working Group (GRWG) review group consists of members of CIRM's Scientific and Medical Research Funding Working Group, non-California scientists whose duties to CIRM are to evaluate grant applications for scientific merit. The group is made up of a fixed number of members, and another group of "alternates". The functionality of the review system with respect to the scientific review group is as follows.
- FR3.10.1 <u>Assignment of members to an RFA review</u>. For any given RFA, only a subset of the members of the GRWG review group will be available to attend the review meeting, and so the system must allow staff members to assign particular members of the group to an RFA.
- FR3.10.2 Reviewer-led conflict of interest assessment. Due to CIRM's strict conflict of interest policies, it is imperative that review group members identify any conflicts that they have with individuals associated with a particular application. This includes both the applicant themselves, as well as all key personnel, collaborators, etc. In addition, it is possible that a member of the review group would have a conflict with an entire institution, in which case they would be recused from reviewing any application associated with that institution. Therefore the system must provide an interface for members of the scientific review group who have been assigned to review an RFA to identify conflicts with all individuals associated with every application submitted for an RFA, as well as every institution associated with every application. The system must provide an interface for staff members to see which reviewer is in conflict with which application.
- FR3.10.3 <u>Reviewer expertise/preference assessment</u>. For some RFAs, but not all, it will be helpful for members assigned to an RFA to self-identify their particular expertise and preferences in reviewing particular applications. Therefore the system must provide a means for staff members to preliminarily assign grant applications to scientific reviewers, in order for them to submit their expertise and preferences. The system must provide reviewers with an interface to make these choices, which are the following: 1. I prefer to review this application; 2. I prefer not to review this application; and 3. I have identified a conflict with this application. In order for the reviewer to make this assessment, the system must provide them with

the ability to view non-proprietary information associated with each grant application. This information includes the applicants name and institution, the names of personnel associated with the application, the scientific abstract, the lay abstract, and the statement of benefit to California. Item #3 above is provided in case some information in the public data has alerted the reviewer to a conflict which they have with this application, which was not identified earlier. Once members have made their choices for the applications assigned to them, this information must be available to staff members to aid in the actual assignment of applications to reviewers.

- FR3.10.4 <u>Assignment of applications to reviewers</u>. Once the scientific reviewers have identified their conflicts and their preferences for review, the system must provide a means for staff members to assign grant applications to reviewers for review. Each application must be able to be assigned to many different reviewers, and of course, each reviewer must be able to have many applications assigned to them. The system should not allow staff members to assign applications to reviewers where the reviewer has identified a conflict of interest which would preclude them from reviewing the application. A reviewer assigned to an application is assigned as either the primary reviewer, or a secondary reviewer. Each application must have one primary reviewer from the scientific review group.
- FR3.10.5 <u>Reviewer access to non-conflicting application data (PDFs)</u>. Once the applications have been assigned to reviewers, the system must provide the reviewers with access to the complete application as a PDF file. Reviewers should be able to see all of the grant application PDF files for those applications with which they do not have a conflict.
- FR3.10.6 <u>Preliminary review interface</u>. Based on the criteria that the scientific reviewers are required to complete (see FR3.7.1), the system must provide an interface for reviewers to enter their critiques. The system should provide the interface in such a manner that reviewers can begin their critique, save their work, and come back to finish the critique at a later date. The system must provide a means for the reviewer to indicate that they are finished with their critique.
- FR3.10.7 <u>Reviewer access to other reviewer comments</u>. Reviewers must be able to see the other critiques of the applications for which they are assigned.
- FR3.10.8 <u>Per-application notes</u>. The system should provide reviewers with a way to take notes on the discussion of each application, during the review meeting. These notes must be tied to an individual application, and must be stamped with the date and the reviewer who made the note.
- FR3.10.9 <u>Final review interface</u>. When discussing an application which the member has been assigned as a reviewer, the system must provide an easy way for the member to view their preliminary review, as they will be required to summarize their review for the benefit of the other members, during the meeting. In addition, the system may provide the ability for reviewers to provide a final score to each application for which they do not have a conflict of interest. These scores will be entered after the discussion of the application during the review meeting. If provided, the system must prevent reviewers from entering a final score for those applications with which the reviewer does have a conflict. Also, the system should then provide some ability for staff members, during the meeting, to ensure that reviewers are all looking at, and scoring, the same application.
- FR3.10.10 <u>Staff-side Recommendation interface</u>. If the system provides functionality for reviewers to enter final scores, the system should provide an interface for staff members to see the scores given, along with an average score, for the application. In addition, the system should provide a means for staff members to assign each application to one of three recommendation categories: 1. Recommended for funding; 2. Recommended should funds be available; and 3. Not recommended for funding at this time. During the meeting, there will be discussion and movement of individual grant applications from one category to another, and so the system should provide an interface for staff members which makes this process as fluid as possible. In addition, it is likely that this interface will be projected onto a screen during the meeting, and so it is imperative that the interface for assigning applications to categories must not show individual scores, but only the average.
- FR3.11 <u>Scientific specialist review group</u>. The scientific specialist review group is an ad-hoc group whose membership will change continuously. These are scientists recruited by CIRM to provide reviews of grant applications which suit their specific expertise. They are non-voting members who also do not give final

- scores. The functionality requirements for this group are essentially a subset of the requirements for the scientific review group, and are outlined below.
- FR3.11.1 <u>Assignment of members to an RFA review</u>. As with scientific review group members, the system must provide an interface for staff members to assign from the group to a particular RFA review. The number of specialists assigned to a particular RFA is not fixed, and may range from zero up.
- FR3.11.2 <u>Specialist expertise/preference assessment</u>. The system must provide staff members with the ability to preliminarily assign applications to specialists, so that the specialists can indicate their particular preferences to review each application. The interface for this functionality should match that of FR3.10.2.
- FR3.11.3 <u>Assignment of applications to specialists</u>. The system must support the ability to assign each specialist any number of applications to review, and each application may be assigned to zero or more specialists. Specialists are always secondary reviewers, never primary.
- FR3.11.4 <u>Specialist access to assigned applications data (PDFs)</u>. Once specialists have been assigned to review particular applications, the system must provide them with the ability to view those applications in full as PDF files. The system must not allow specialists to see any applications except those which they have been assigned to review.
- FR3.11.5 <u>Specialist review interface</u>. Using the criteria as defined in FR3.7.1, the system must provide specialists with an interface to create/edit their review. Like the scientific review group, the system should provide specialists with the ability to edit their review over time, and then indicate when they have finished the review. Specialists provide a preliminary score of an application, but do not give final scores. The system should provide specialists with an easy way to view their reviews, as they will be required to summarize their review for the working group at the review meeting.
- FR3.12 <u>Patient Advocate review group</u>. The patient advocates are a seven-member subgroup of the ICOC, whose role is to advise CIRM and help guide CIRM's policies from the standpoint of those people who are the reason CIRM exists, the patients. With respect to the system, patient advocates have a different role from other review groups. They are invited to participate in each review meeting, but they are non-voting, non-reviewing members. In addition, they are also full members of the ICOC, and thus participate and vote in the final disposition of each application (See FR3.13).
- FR3.12.1 Patient Advocate conflict of interest assessment. Like most other review groups, the patient advocates are required to self-identify conflicts of interest with grant applicants and their institutions. However, whereas the scientific review group conflicts are defined primarily via scientific collaboration, the patient advocates conflicts of interest are solely financial. In either case, the system must provide an interface for the patient advocates for identifying any conflicts of interest they may have with both the individuals associated with any applications for a particular RFA, and any institutions associated with any applications. Any conflicts identified will recuse them from viewing any application associated with the conflicting individual or institution.
- FR3.12.2 <u>Patient Advocate access to non-conflicting application data (PDFs)</u>. Once patient advocates have identified their conflicts of interest, the system must provide them with the ability to access any application for which they are not in conflict, in PDF form.
- FR3.13 <u>ICOC</u> review group. The ICOC "review group" is not in actuality a review group at all, but is the final decision-making body with regard to which applications to fund. However, their activities relative to this decision process share a number of similarities with those of the other review groups, and so it may be efficacious to group these activities as a "review group". Once all other relevant review groups have had their review meetings and generated their recommendations for each application, a meeting of the ICOC will be scheduled to discuss the applications and make the final funding decision.
- FR3.13.1 <u>Conflict of interest assessment.</u> Prior to the ICOC meeting, members must identify any conflicts of interest they may have with either the individuals or institutions associated with each application. Therefore the system must provide an interface for ICOC members to indicate their conflicts with every individual associated with each application, along with every institution associated with each application. ICOC members who have identified conflicts with any individuals or institutions will be recused from voting and discussion of any application associated with those individuals or institutions. Therefore the

system must provide an interface for staff members to see which ICOC members are in conflict with which applications.

FR3.13.2 <u>ICOC</u> access to <u>Public Summaries</u>. ICOC members (except for patient advocates, as outlined in FR3.11), will not have access to the grant applications themselves. Rather they will have access to the staffgenerated public summaries, as described in FR3.8.2. As these summaries are publicly available, the system does not need to take conflicts of interest into account when determining whether ICOC members will have access to the summary.

FR3.13.3 <u>Per-application notes</u>. The system may provide an interface for ICOC members to write notes on the discussion of each grant application. These notes will only be for the personal use of the ICOC member themselves, to aid in their voting.

FR3.13.4 <u>Final funding decision</u>. At the ICOC meeting, after the grant applications have been discussed, the ICOC members will vote on whether to fund the application. The system may provide an interface for members to vote on individual applications. In addition, it may be the case that the ICOC will vote en bloc to fund or not fund a group of applications. This determination will be recorded via role-call vote. Therefore, the system may provide an interface for staff members to change the status of grant applications to "Funded" or "Not Funded" en bloc.

FR3.14 Other review groups. The reviewer groups outlined in FR3.10 – FR3.13 constitute those groups which are known at this time. However, the system may also provide the ability to create new review groups with their own particular functionality as the need arises.

FR4: Grants Management Functional Requirements

Section/ Requirement ID	Requirement Definition	Requirement
FR4.1	Ease of navigation	Should
FR4.2	Financial projection tool	Should
FR4.3	Bond issues	Must
FR4.4	Assurances	Must
FR4.4.1	Assurances must have an expiration date	Must/Should
FR4.5	Grant record metadata	Must
FR4.5.1	Grantee "success" metadata	Must
FR4.5.2	Demographic metadata	Should
FR4.6	Complex coding system	Must
FR4.6.1	Coding system should be hierarchical	Must
FR4.6.2	Coding should be weighted	Should
FR4.7	View/edit grant status	Must
FR4.8	Create/edit per-RFA grant requirement workflow tasks	Should
FR4.9	Financial data modification	Must
FR4.10	Generate Notice of Grant Award	Must
FR4.11	Payment tracking	Must
FR4.11.1	Generate payment memo	Must
FR4.11.2	Update payment memo	Must

Section/ Requirement ID	Requirement Definition	Requirement
FR4.12	Create/edit/delete GM attachments to grants	Must
FR4.12.1	Documents	Must
FR4.13	Email templates	Should
FR4.13.1	Create/edit templates	Should
FR4.13.2	Create/edit email schedule/trigger	Should

- FR4.1 <u>Ease of navigation</u>. In order to streamline staff activities, the system must support the ability to quickly go from viewing a particular grant, to viewing any piece of data relevant to that grant, such as progress reports, staff-written notes, etc. Ideally, the system should be hyperlinked to allow quick navigation from any one item, to any other related item.
- FR4.2 <u>Financial projection tool</u>. In order to aid in CIRM's grants budgeting and forecasting, there is a need to have the capability to perform financial projections, such as cash flow analysis, the impact of projected future RFA's, etc. The system should either provide such a system, or provide the capability to interface to an external system. This interface should at a minimum consist of an automated or simple data export capability.
- FR4.3 <u>Bond issues</u>. CIRM receives its funding in the form of state bond issues, and it is important that we be able to tie individual grants back to the bond issue used to fund them. Therefore, the system must support the ability to store information on bond issues, and tie individual grants to a particular bond issue.
- FR4.4 <u>Assurances</u>. Due to the nature of the work that CIRM grantees will be doing, often we will require grantees to submit a variety of "assurances", which signify that they are allowed to carry out certain research. The system must have the ability to define various assurance types, attach those types to RFA's, and then, for each grant, store data on whether each assurance is required for that grant, and the status of our receipt of the assurance.
- FR4.4.1 <u>Assurances must have an expiration date</u>. Assurances must have, in addition to other data, an expiration date. The system must provide a means of reporting on which assurances are due to expire in a given time. Ideally, as outlined in FR1.1.2, the system should provide an automated trigger that will send an email notifying staff that a particular assurance will expire at a given time in the future.
- FR4.5 <u>Grant record metadata</u>. Staff members must have the ability to add custom data to each RFA, which would then be stored on a grant-by-grant basis. This will allow staff members to track arbitrary metadata on the grants.
- FR4.5.1 <u>Grantee success metadata</u>. For CIRM to be able to adequately track the progress of its programs, it is important that we be able to track the success of our grantees in areas such as publications, patent applications, Investigational New Drug (IND) records, licensing agreements, and patent or licensing income. While we may rely on some measure of self-reporting of these items through the progress reports system, there is also a need for staff to be able to modify and add to these data items manually. Therefore, the system must provide a capability for staff members to add and modify additional data items to grant records, and these items must be available to the reporting system.
- FR4.5.2 <u>Demographic metadata</u>. Another set of data that CIRM would like to track is a variety of demographic data about the grant, including items such as the number of women and under-represented minorities included in the grant. This data may be requested of the applicant within the application form (and subsequently through progress report forms). The system should provide the ability for administrative staff to enter demographic-type metadata about each grant.
- FR4.6 <u>Complex coding system</u>. For purposes of programmatic management and portfolio analysis, it is important that CIRM be able to code individual grants to various categories, such as diseases, type of research, etc. Therefore the system must support a complex system of coding of individual grants.

- FR4.6.1 <u>Coding system must be hierarchical</u>. Due to the complexity of CIRM's coding needs, the system must permit a hierarchical coding scheme. For example, one part of our coding scheme could consist of "Diseases -> Neurological Diseases -> Autism". The system must allow the grant to be coded to any of these three categories/subcategories.
- FR4.6.2 <u>Coding should be weighted</u>. Because a grant won't always be completely relevant to a particular coding, it would be helpful if the system allows the coding to be weighted. For example, if the grant were to be given an "Autism" coding, the system should allow that coding to also be weighted to, say, "20%".
- FR4.7 <u>View/edit grant status</u>. The Grants Management Officer is responsible for changing an applications status from application to grant, and therefore the system must allow the GMO to view and edit the status of an application/grant.
- FR4.8 <u>Create/edit per-RFA grant requirement workflow tasks</u>. Grant programs will all have unique requirements for defining the steps/tasks necessary for the grant to be considered ready to pay. These tasks may include supplying certifications and other documents, signing and returning the Notice of Grant Award (See FR4.10), and other items. The GMO must be able to define these tasks on a per-RFA basis. The system should allow the defined requirements to be enabled/disabled based on data contained within the grant application form, in a fashion that can be overridden by the GMO.
- FR4.9 <u>Financial data modification</u>. Because it is often the case that there will be changes between the budgets requested by a grantee in their application, and the amounts actually approved for funding, it is a requirement that the system allow changes to be made to budget data. It is also important that the system retain the original, requested, budget numbers for historical and reporting purposes. Therefore, the system must support the ability to modify budget data for a given grant, while retaining all original budget data. The GMO must be able to edit the budget data supplied by the grantee, whether to make corrections to the grantees calculations, or to distribute adjustments made to the requested amount. Any such changes must be kept in a permanent date and user-stamped audit log.
- FR4.10 Generate Notice of Grant Award. Once an application has been approved for award, the GMO will step through the application, searching for missing/incorrect data and unfulfilled requirements (see FR4.8). After the grant has been vetted, and all of the requirements (see FR1.1.1) have been met, the GMO will generate a Notice of Grant Award letter. The system must support the generation of this letter, based on a template, and the result should be a Microsoft Word document. The GMO will manually send the grantee the letter via mail.
- FR4.11 <u>Payment tracking</u>. The system must have the capability to track and report on individual payments made, payments due, etc.
- FR4.11.1 <u>Generate payment memo</u>. Once a GMO has determined that all applicable requirements for a particular pay cycle have been met by the grantee, the system must allow the GMO to generate a payment memo, to be sent to the SCO. The contents of the payment memo are outlined in Section 4.1.3. At the current time the payment memo must be generated as an Excel spreadsheet, which will then be manually sent to the SCO.
- FR4.11.2 <u>Update payment memo</u>. Once the SCO has paid the grantees, they send back to CIRM a file which includes the check # used to pay for each payment record. The system must provide a means to update its payment records with these check #'s.
- FR4.12 <u>Create/edit/delete GM attachments to grants</u>. Often in the course of working with a particular grant, it will be important for a GMO to be able to make a note or attach information to a particular grant. Therefore the system must allow the attachment of both notes and other documents to a particular grant. Both types of attachments must be date and user stamped.
- FR4.12.1 <u>Documents</u>. The system must allow the GMO to attach an arbitrary number of documents to a grant. Each attached document must include, at a minimum, a text description of the document. The system should not restrict either the number, type, or size of document attached.
- FR4.13 <u>Email templates</u>. In addition to the system level email templates outlined in FR7.4, the grants management module of the system should allow GMO's to define their own email templates and schedules.

- FR4.13.1 <u>Create/edit templates</u>. GMO's should be able to create and edit email templates specific to their needs. These templates should either be defined per-GMO, or per-program.
- FR4.13.2 <u>Create/edit schedule/trigger</u>. The GMO should also be able to define a separate schedule, on a per-program basis, for delivering the email templates defined above.

FR5: Progress Reporting Functional Requirements

Section/	Requirement Definition	Requirement
Kequitement ID	Requirement Deminuon	Requirement
FR5.1	Multiple reports per-RFA	Must
FR5.2	Regular schedule	Must
FR5.2.1	Schedule configurable per-RFA	Must
FR5.3	Arbitrary attachments	Should
FR5.4	Paged interface	Must
FR5.5	Broad set of field types	Must
FR5.6	Complex budget	Must
FR5.7	Completed report available as PDF	Should/May
FR5.8	Staff notes	Must

FR5 <u>Progress Reporting</u>. The progress reporting module allows grantees to fill and submit regularly recurring progress reports, including both financial progress and program progress reports. From a system design standpoint, the functional requirements of the progress reporting module are almost identical to the application module, in that the system will present the grantee with a multi-page, complex form consisting of an arbitrary amount of data fields. Progress reports are generally broken into two main categories of data: a financial progress report which will detail the amount expended since the last report, and a program progress report, which will detail the scientific progress made during the covered time period. The requirements that are unique to the progress reports system are outlined in items FR5.1 through FR5.2 below.

- FR5.1 <u>Multiple reports per-RFA</u>. It is important that the system allow multiple progress report definitions to be attached to each RFA. It may be necessary, for example, to break the financial reporting into a separate progress report from the program reporting. Or there may be a preliminary financial report which collects different data than a final report. Therefore, the system must allow multiple progress report types to be defined and required on a per-RFA basis.
- FR5.2 <u>Regular schedule</u>. The progress reports will be required to be submitted on a regular (usually semi-annual) basis. Therefore the system must support defining a schedule of progress report due dates. The system must allow grantees to submit progress reports past their due date, and must support querying for past-due reports.
- FR5.2.1 <u>Schedule configurable per-RFA and per-report</u>. The system must allow progress report due dates to be defined on a per-RFA and per-report basis.
- FR5.3 Arbitrary attachments. See FR2.5.
- FR5.4 Paged interface. See FR2.6.
- FR5.5 Broad set of field types. See FR2.7.
- FR5.6 Complex budget. See FR2.8.
- FR5.7 Completed report available as PDF. See FR2.9.

FR5.8 <u>Staff notes</u>. Administrative staff must be able to attach notes/comments to each individual progress report. These notes should also be searchable.

FR6: Reporting Functional Requirements

Section/ Requirement ID	Requirement Definition	Requirement
FR6.1	Report types	Should
FR6.1.1	Standard reports	Must
FR6.1.2	Custom reports	Should
FR6.2	Common reports	Must
FR6.2.1	Financial reports	Must
FR6.2.2	Workflow "guard"/check reports	Must
FR6.2.3	Completed/closed grant reports	Must
FR6.3	System data accessible to query system	Must/Should
FR6.4	Role-based access	Should
FR6.4.1	Standard reports	Should
FR6.4.2	Custom reports	Should/May
FR6.5	Export results	Should

- FR6.1 <u>Report types</u>. The reporting requirements for the system encompass two types: Standard reports, and ad-hoc Custom reports. Both Standard and Custom reports should support parametric input data.
- FR6.1.1 <u>Standard reports</u>. Standard reports are the most commonly used reports, and should be easily and quickly available to administrative users. Because they are envisioned to be reports that will be run often, but created rarely, it is acceptable if the creation of standard reports is somewhat more difficult, or requires external configuration, as a trade-off to allowing greater power and flexibility in the type of reporting. The system must support the creation of standard reports.
- FR6.1.2 <u>Custom reports</u>. Custom reports should have an interface that allows non-technical administrative users to pull the data they need from the system. Therefore the system should support the ability of administrative users to create new reports on an ad-hoc basis, through the administrative interface. The system should support at least a basic report layout engine, to allow the user some ability to customize its appearance.
- FR6.2 <u>Common reports</u>. The following subsections give information on some of the more common types of reports that CIRM will require.
- FR6.2.1 <u>Financial reports</u>. For purposes of analyzing CIRM's progress, it is important that the reporting system have the capability of pulling information on a variety of financial data. This data includes (but is not limited to) funding by RFA (both funds paid and funds committed), funding by fiscal year, funding by "initiative" (see FR2.1.1), grants funded by bond issue, level of financial commitment, etc. Therefore, the system must provide the ability to report on complex financial data, and include features for summing, grouping, etc.
- FR6.2.2 Workflow guard/check reports. As outlined in FR1.1.1, the system must have a concept of various checks that a grant must pass before moving from one phase to another (or at least before moving to payment). For reporting purposes, the system must support reporting on the status of each grants requirements or checks.
- FR6.2.3 <u>Completed/closed grant reporting</u>. The system must keep track of the status of grants throughout their entire lifecycle, and must therefore allow for reporting on completed / closed out grants.

- FR6.3 System data accessible to query system. The reporting system must support pulling data from virtually any part of the system, and allow the manipulation and filtering of that data to allow the creation of whatever types of reports the user requires. In addition, the system should support role-based access to the underlying data. If the proposed system does support role-based access, at a minimum it should support restricting access on a table-by-table basis, and ideally would support restricted access based on settable criteria. If the proposed system does not support role-based data access, then the custom reporting system must be limited to reporting on to-be-defined non-proprietary information.
- FR6.4 <u>Role-based access</u>. Access to the reporting system must be limited to administrative users. In addition, the authorization to create, edit, and run reports should be role-based (see FR7.1.3).
- FR6.4.1 <u>Standard reports</u>. Authorization of the standard report system should be two-fold: authorization to create/edit reports, and authorization to run reports. Ideally the system will allow role-based authorization on a report-by-report basis.
- FR6.4.2 <u>Custom reports</u>. Authorization of the custom report system should also be two-fold: authorization to create/edit reports, and authorization to run reports. Ideally the system will allow role-based authorization on a report-by-report basis.
- FR6.5 Export results. The result of running a report should return an HTML document with the generated report data to allow administrative users to quickly view results. However, it is important that the system also allow report results to be exported in a variety of formats for other purposes. At a minimum, the system should support the exporting of report results in the following formats: Email template (see FR7.5.2), Microsoft Word document, Microsoft Excel spreadsheet, and Adobe PDF file.

FR7: Administrative Functional Requirements

Section/ Requirement ID	Requirement Definition	Requirement
FR7.1	Authentication & Authorization	Must
FR7.1.1	Username/password-based authentication	Must
FR7.1.2	IP-based access control	Should
FR7.1.3	Role-based authorization	Must/Should
FR7.2	System configuration	Should
FR7.3	Edit user profile data	Must
FR7.4	Create/edit email templates	Should
FR7.5	Create/edit automated/triggered tasks	Must/Should
FR7.5.1	Emails	Must
FR7.5.2	Emailed reports	Must
FR7.6	New grant programs	Should

- FR7.1 <u>Authentication & Authorization</u>. The administrative interface to the system must support rigorous and secure methods of authentication and authorization. Because the administrative interface will be used by internal employees only, it is acceptable to impose greater restrictions on password lengths, etc. in order to increase security.
- FR7.1.1 <u>Username/password-based authentication</u>. For web-based portions of the system, the system should at minimum support form-based (i.e. not "Basic" or NTLM) authentication, over an SSL-encrypted channel. Usernames should be email addresses. The following are minimum strength requirements for passwords which must be system-enforced: minimum length of 6 characters; minimum of at least 1 numeric and 1 symbolic character; alpha characters must contain both cases; password longevity no longer

than 6 months. These settings should be configurable in the system, ideally through the administrative interface itself.

- FR7.1.2 <u>IP-based access control</u>. The system should support limiting administrative access via IP address. This would be an adjunct to the password-based authentication, rather than an alternative. This ability should be simple (i.e. a list of allowed IP addresses), flexible (i.e. the list should allow wildcards to specify entire networks), and easily configurable through the administrative interface itself.
- FR7.1.3 <u>Role-based authorization</u>. The ability of an administrative user to access the administrative functionality of the system must be based on a notion of user roles. The system must support the ability to assign administrative users to a single role. The system should support the ability to assign users to multiple roles, with their authorization based on the union of the authorizations of the roles assigned. The system should also allow the association of roles to functionality to be configured, ideally through the administrative interface itself.
- FR7.2 <u>System configuration</u>. Many of the administrative tasks users will need to perform will be based on the particular structure of the final system, and as such cannot be enumerated here. However, the system should allow as many configuration and customization tasks as possible to be performed through the webbased administrative interface. For those tasks which can be performed through the interface, the system must enforce the authentication and authorization requirements outlined above. For those tasks which must be performed outside of the system, the system design should make those tasks as simple as possible, and, to the extent possible, those configuration changes should be dynamically applied to the running system (i.e. should not require restarting the system).
- FR7.3 Edit user profile data. Properly authorized administrative users must be able to edit the profile data of the various users of the system, including other administrative users. The authorization to edit administrative user profiles must be different from the authorization to edit other profiles. At a minimum, the system must allow users to edit non-administrative users passwords and contact information (email addresses, physical addresses, and telephone numbers). The system must also allow authorized administrative users to edit other administrative users role assignment(s).
- FR7.4 <u>Create/edit email templates</u>. Administrative users must have the ability to create and edit the various email templates used throughout the system. The system should present the administrative user with an easy to use web-based tool for editing those templates, though other means will be acceptable.
- FR7.5 <u>Create/edit automated/triggered tasks</u>. The system must enable authorized users to create and edit a variety of automated tasks. At a minimum those tasks must be fired by the following triggers: 1. date-based trigger, including a supplied adjustment value (i.e. *n* days before the due date of a progress report, or *n* weeks after submission of an application), and 2. task-based trigger (i.e. task triggered immediately after a user finishes one of their assigned tasks). Ideally the system will provide a flexible, configurable automated task system which will allow CIRM to customize the tasks in a myriad of ways (for example, a rule-based system, as detailed in FR1.1.2). In addition, the system should support a variety of tasks or events that can be triggered through the system. At a minimum, the system must support the following two types: emails using an email template, and standard reports.
- FR7.5.1 <u>Emails</u>. One of the most common use cases of the automated task system is to have the system automatically generate and send emails based on a variety of conditions. The system must support the sending of automated emails after various events (i.e. submission of LOI, Application, or Progress Report), as well as reminder emails (Progress Report reminder, reminder to GMO that a payment cycle is upcoming, etc.)
- FR7.5.2 <u>Reports</u>. The system must support the ability to automatically generate a Standard report (see FR6.1.1) and email the results to one or more users, either administrative users or others.
- FR7.6 New grant programs/RFAs. A key requirement of the system is to allow for the creation of new grant programs, with all of the changes and requirements necessary therein (i.e. new LOI requirements, new Application forms, potentially new Review groups, etc.). To the extent possible, the system should allow for creating new programs within the administrative interface. And the system should allow non-technical users to do as much of the work of creating a new program as possible.

OTHER REQUIREMENTS

This section contains the detailed requirements of the system that are not specific to any functionality. These include such requirements as data integrity, low-level security, system availability, etc.

Interface Requirements

The interface requirements include both the user interface to the system, as well as programmatic and low-level interfaces that the system uses for communications with other systems.

4.1.1 User Interfaces

As stated in the constraints section (Section 1.4), the web-based portion of the User Interface (UI) for the system must comply with Federal Section 508 accessibility standards. In addition, the portions of the system UI used by external clients (applicants, grantees, reviewers, and the general public) must be fully functional across all major operating system/browser combinations. The UI of the administrative sections, if web-based, may be functional across all the same combinations, but it must be functional with Internet Explorer 6 and above, running on Windows XP Professional or Windows Vista.

4.1.2 Software Interfaces

While currently there is no need for the system to interface with other software systems, at some point in the future there may be a need to connect to an accounting package. Therefore the system must be capable of interfacing to a variety of accounting systems with a minimum of configuration effort. And the system should be capable of interfacing with a variety of other software through some form of extension API.

4.1.3 Communications Interfaces

Currently the only identified communications requirement is between the system and the California State Controllers Office (SCO), which is the group that handles our payment processing. At the appropriate times, the system must generate a pay memo which is sent to the SCO, and which lists a variety of information regarding the grant (see below), the amount to be paid, and the date. After processing the transaction, the SCO will send back a similar list, with the date the warrant (the state version of a check) was paid and the warrant number added. This information will then be imported back into the system, so that the actual pay date can be reported on.

The information included in the pay memo is:

Grant Number

Fund Year

Installment #

Grantee ID

Payee Name

Payment Recipient

Recipient Title

Street Address

City, State, Zip

Payment Amount

Data Conversion Requirements

While the CIRM is still a young agency, we have a certain amount of legacy data from the first four grant programs we have funded: 1. training grants; 2. SEED research grants; 3. COMPREHENSIVE research

grants; and 4. Shared Research Laboratory grants. This data is currently held in a mixture of a Postgres database, PDF forms, and Excel spreadsheets.

The successful system will be required to integrate this legacy data into the system as first-class data (in other words, the legacy data should be functionally indistinguishable from data created directly in the winning system).

Hardware/Software Requirements

Although CIRM's internal IT infrastructure is a standard Microsoft platform, it is understood that the platform is a secondary aspect to the best fulfillment of the requirements of the system. Therefore, the system may be architected using any mainstream hardware / OS platform (i.e. PC/Windows, PC/Linux, Sun/Solaris, etc.)

Application Programming Interface (API) Requirements

In order to provide the most flexibility for CIRM's future needs, the system should expose an extension API. At a minimum, this API should support the ability to pull data from the system, through the use of a query/retrieval interface. For example, the system should allow a query for grant records based on an institutional name, which would return a list of grant IDs; there should be another API that, given a grant ID, will return information on that grant.

Ideally, the API exposed should support adding data to the system as well as querying.

Operational Requirements

Operational requirements entail those factors that affect the systems core availability and robustness. The successful response to this RFP may be either a hosted solution, where the respondent or their designee (upon prior approval) hosts the system, or a "self-hosted" system, where CIRM takes responsibility for hosting the system. If a hosted system is envisioned, extra requirements will be placed on the respondent for assuring the reliability and availability of the system (see sections "Reliability" and "System Availability" below).

In either case, the respondent should include in their proposal an indication of the type and degree of support required by the system.

Security and Privacy

As the system will include sensitive research data as well as financial information, ensuring the security of the system is of paramount importance.

- A. Types of security required.
 - a. Physical security. If the proposed system is to be a hosted solution, the system must be physically secured against access to any unauthorized personnel. Such personnel consists of the respondents IT staff, the IT staff of the respondents designee for hosting, if applicable, and CIRM's IT staff. Typical adequate physical security would be a cage in a mainstream ISP or Co-location facility. Single-cabinet security is in general not adequate and must be justified. Similarly, the physical security offered by hosting within the respondents offices is not acceptable. In addition to the security provided, the system should provide an audit of physical access in the form of video security cameras.
 - b. Secure authentication. All users of the system must be authenticated using a username/password combination. User passwords should conform to certain minimal standards of uniqueness, including a minimum length of 6 characters, and a requirement that at least one character be either numeric or a symbol.
 - c. Secure communications. All web-based communications with the system must take place over a secure communications channel. This channel should at a minimum conform to the SSL 3.0 standard. In addition, should the respondent propose a hosted solution, and furthermore propose a form of network-based backup in which data is sent over the

- public Internet, this communication must take place over a secure communications channel.
- d. Role-based authorization. In addition to proper authentication, all users of the system should be members of one or more roles, and all access to functionality of the system should be authorized against these roles. The system must not allow users to access data that is not authorized, given their role. In addition, applicants/grantees must not be able to access any data that is not related to their applications/grants.

Audit Trail

All substantive changes to data in the system should be recorded in a User ID and date-stamped audit log. Substantive changes consist of, but are not limited to, changes made by an applicant to their application, updates to a reviewer's review of an application, or user profile changes. In addition, the following changes must be recorded in a User ID and date-stamped audit log:

- Any changes made to a grant by a staff member, including but not limited to, any budget changes, changes in number, type, or role of any personnel listed on the grant.
- Any changes made to a users profile by a staff member. For example, the system should allow
 administrative staff members to reset the password of an applicant, grantee, or reviewer. This
 change must be audited.
- The use of any capability offered by the system to circumvent the normal data channels. As an example, should the system allow staff members to alter a reviewer's review, this alteration must be audited.

Reliability

As the system will be responsible for tracking and managing roughly three (3) billion dollars in grants and loans, which represents the core of CIRM's mission, it is critical that the system provide the utmost in reliability. For the purposes of this section, "reliability" is specifically defined as the full, proper functioning of the system in its entirety. There are two major groupings of factors involved in a reliable system: hardware and software. Thus the responsibility of the respondent for fulfilling the reliability requirements of the system varies depending on whether a hosted or a self-hosted (CIRM-hosted) solution is proposed.

In the case of a hosted solution, the system must maintain a reliability of at least 99.5%. This equates to no more than 44 hours of system unavailability per year.

In the case of a CIRM-hosted solution, the system must maintain a software reliability of at least 99%. This means that the system must not be unavailable for more than 88 hours per year, due to software failures.

Recoverability

Recoverability entails the ability of the system to recover from a variety of faults, ranging from small-scale outages such as a system reboot, to catastrophic failures such as physical destruction of the systems hardware. The following minimum recoverability capabilities are required for any respondent:

- A. In the event of system downtime due to a software error, system functionality must be restored within 72 hours of failure detection, and should be restored within 24 hours.
- B. In the event of database corruption, the system must be capable of being restored to its condition of no more than 15 minutes before the corruption occurred.

The following minimum recoverability capabilities are required for any respondent who proposes a hosted solution:

A. In the event of physical failure of any non-redundant hardware subsystem, or the complete failure of a redundant subsystem, the system must be restored to functionality within 72 hours of failure detection.

B. In the event of catastrophic destruction of the hosting site, the system must be restored to functionality within one (1) week of the destruction of the site. In addition, the system database must be restored to its condition of no more than two (2) days prior to the destruction of the site. This will require some form of off-site storage of backup data.

System Availability

The system must be generally available to users 24 hours a day, 365 days a year. In the event of required system downtime, such downtime must take place between the hours of 6:00 p.m. and 7:00 a.m. Pacific time Monday through Friday, or anytime during the weekend. If the system is to be hosted and/or administered by the respondent or their designee, any scheduled downtime must be coordinated with CIRM and users of the system notified of the downtime in advance. During system downtime, the web-based portion of the system should present an informational page to users notifying them that the system is down, and expected to be available at a given time.

As all of CIRM's staff and all of the applicants/grantees are California-based, it is most important that the system be available during general business hours in the Pacific time zone.

General Performance

General performance of the system must meet commonly accepted minimums. Specifically, average response time for any page request (counting from the moment of request until the browser completes rendering the page) should be no more than 2.5 seconds. In addition, the average response time for "standard" report queries should be under 8 seconds.

Capacity

Over the course of its 10-12 year lifetime, CIRM expects to run several hundred different grant programs. As many of these grants will be for time periods of 3 or more years, a significant percentage of all grants will be active at any one time. The system must be capable of scaling to encompass this volume of data and user activity.

The system must be capable of supporting at least 100 simultaneous users, of which up to 35 will be administrative users. In addition, the system must be capable of supporting at least 10,000 registered users.

Data Retention

The data within the system is of critical importance to CIRM's mission, and therefore this data must be retained and accessible online during CIRM's entire lifetime. More specifically:

- A. Grant application records, grant records, user records, grant review records, and any other data core to the system must be retained for the lifetime of the organization.
- B. Audit log records must be retained for CIRM's lifetime.
- C. Web access records must be retained for 1 year.
- D. System documentation, including logs of system-level changes, must be for CIRM's lifetime.

Error Handling

Errors occurring in the system should minimize disruption of user activity on the system. At the same time, all errors should be logged, and severe errors should be automatically brought to the attention of the responsible party.

If an error occurs during the handling of a user request, such that the request cannot be fulfilled correctly, the user must be made aware of the error in an unobtrusive manner, and the user should be able to continue their session.

Errors must be classed in order of severity. Notification of serious errors must automatically be sent to the appropriate person. In addition, the administrative user interface should allow authorized users to view the error log.

Source Code

Although not required for a successful response to the RFP, access to and a license for CIRM to extend and use the source code of the system, with the license surviving any dissolution of the respondent organization, will be considered highly valuable. Alternatively, having source code for the system placed in escrow, to be given to CIRM for our use in supporting and extending the system in the event of the dissolution of the respondent, or in the event that the respondent ceases to support the system, will be highly valued.

APPENDIX A - GLOSSARY

The following is a concise glossary of acronyms used in this document.

- API Application Programming Interface. An Application Programming Interface is a source code interface used to communicate with and request services of a computer program or system. It is only descriptive. A particular program or system *implements* a given API if it provides the functionality described by the API.
- CIRM California Institute for Regenerative Medicine. CIRM is a new state agency tasked with making grants and providing loans for stem cell research, research facilities and other vital research opportunities.
- DGMS *Director of Grants Management Systems*. CIRM's DGMS will be responsible for leading the technical development of the system, and will be the primary point of contact for the respondent at CIRM.
- GMO Grants Management Officer. GMO's are responsible for the business management and other non-programmatic aspects of grant awards, including evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; providing consultation and technical assistance to applicants and grantees, including interpretation of grants administration policies and provisions; and administering and closing out grants.
- ICOC Independent Citizen's Oversight Committee. The ICOC is CIRM's 29-member governing board.
- ISP *Internet Service Provider*. ISP's are businesses or organizations that provide customers with access to the Internet and related services, such as co-location of servers.
- LOI Letter of Intent. An LOI is a non-binding declaration that a particular person or entity intends to submit an application for a particular grant program.
- RFA Request for Application. An RFA is an official solicitation by CIRM for applications directed to a particular funding opportunity. Each RFA will specify the objectives and requirements that apply, and the review criteria that will be used to evaluate the merits of applications submitted in response to the announcement.
- RFP Request for Proposal. An RFP is an invitation for suppliers, through a bidding process, to bid on a specific product or service. Among other things, RFP's for computer software usually include a list of required functionality in the form of a functional specification document (this document).
- SCO State Controllers Office. The California State Controllers Office currently acts to disburse the funds CIRM gives out to its grantees.
- SO *Science Officer*. The Science Officers of CIRM are responsible for all of CIRM's grants administration and management.
- SSL Secure Sockets Layer. The Secure Sockets Layer is a standard protocol layered on top of TCP which provides for both authentication and encryption of data.
- TCP Transmission Control Protocol. TCP is the protocol used to provide reliable two-way communications between entities over the Internet.

EXHIBIT 2

Agreement No. CIRM 2060

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE INDEPENDENT CONSULTANT AGREEMENT

	for Rege	GREEMENT to furnish certain consultant services is made by enerative Medicine hereinafter called (the CIRM), and (the Consultant).		
I.	NATUR	URE AND PLACE(S) OF SERVICE		
	A.	The Consultant shall furnish to the CIRM the following descr time schedule by which the Consultant is to produce or provio perform certain consulting services as well as reports on the p	de specified materials or	
	В.	In addition to the services described in subparagraph A. above to the CIRM shall be incorporated herein by reference and ma		
C. If the Consultant is an entity other than an individual, the be assigned to perform the work set fo work to any other individual(s) other than those describe without the written approval of the CIRM.			rein. No reassignment of	
	D.	Place(s) of performance of such services shall be:		
		Consultant's location:	CIRM's location:	
			210 King Street San Francisco, CA 94107	
follows:	E.	The CIRM will provide working space, equipment, furniture,	utilities, and services, as	
II.	TERM (OF AGREEMENT		
	A.	The term of this Agreement shall be from thr	rough	
perform	its respo immedia ons, tion shall	CIRM reserves the right to terminate this agreement subject to consultant. Consultant may submit reement only if the CIRM should ansibilities as provided herein. In addition, this agreement may attely for cause. The term "for cause" shall mean that the Consultant and/or responsibilities of this agreement. In the effective as of the date indicated on CIRC.	t a written notice to substantially fail to be terminated ultant fails to meet the terms	
	C.	The term of this agreement may be extended by the mutual. w	vritten consent of both	

parties.

III. COMPENSATION AND REIMBURSEMENT FOR EXPENSES

- A. The CIRM shall pay the Consultant for services performed on the following basis:
 - 1. Professional Fees::
 - 2. Other Expenses

MAXIMUM TO BE PAID UNDER THIS AGREEMENT

\$

- * Reimbursement for travel and per diem shall be in accordance with established CIRM rates and policies.
- B. Payments shall be made upon the Consultant's submission of invoices indicating the Agreement Number and setting forth charges in accordance with rates detailed in Article III-A. Each invoice shall include the Consultant's taxpayer identification number (Social Security or employer identification number). Invoices shall be submitted in triplicate not more frequently than monthly in arrears to:

California Institute for Regenerative Medicine Chief Finance & Administrative Officer 210 King Street San Francisco, CA 94107

IV. REPORTING

In performing consulting services under this Agreement, the Consultant shall be accountable to the CIRM and shall provide progress reports to CIRM upon CIRM's request.

V. NOTIFICATION

Notices concerning this Agreement shall be addressed as follows:

CIRM:

CONSULTANT:

[Insert name and address]

VI. TAXES

The compensation stated in Article III includes all applicable taxes and will not be changed hereafter as the result of Consultant's failure to include any applicable tax or as the result of any change in the Consultant's tax liabilities. The Consultant acknowledges that compensation payable hereunder may be subject to withholding of state and federal income tax, including state income tax subject to withholding pursuant to California Revenue and Taxation Code Sections 18661-18677.

VII. INDEPENDENT CONSULTANT STATUS

A. Both parties agree that in the performance of this Agreement the Independent Consultant shall not be an agent or employee of the CIRM, shall not be covered by the State of California Worker's Compensation Insurance or Unemployment Insurance, shall not be

eligible to participate in the CIRM's retirement programs, and shall not be entitled to any other CIRM employee benefits.

B. The Consultant shall be solely responsible for the conduct and control of the work to be performed by the Consultant under this Agreement, except that the Consultant is accountable to the CIRM for the results of such work. The Consultant's services for the CIRM shall be performed in accordance with currently approved methods and ethical standards applicable to the Consultant's professional capacity.

California State Contract Code 10515 (a) states: No person, firm, or subsidiary thereof who has been awarded a consulting services contract may submit a bid for, nor be awarded a contract on or after July 1, 2003, for the provision of services, procurement of goods or supplies, or any other related action that is required, suggested, or otherwise deemed appropriate in the end product of the consulting services contract.

VIII. ASSIGNMENT OR SUBCONTRACTING

The Consultant may not assign or transfer this Agreement, or any interest or claim, or subcontract any portion of the work, without the prior written approval of the CIRM. The withholding or granting of such approval is totally discretionary with the CIRM. If the CIRM consents to such assignment or transfer, the terms and conditions of this Agreement shall be binding upon any assignee or transferee.

IX. PROPERTY RIGHTS, INCLUDING PATENTS AND COPYRIGHTS

All written and other tangible material ("Material") produced pursuant to this Agreement by the Consultant shall be considered a work-made-for-hire under the Copyright Act. To the extent said Material does not qualify as a work-made-for-hire, Consultant hereby assigns all right, title, and interest, including, but not limited to, copyright and all copyright rights in the Material to the CIRM and shall execute any and all documents necessary to effectuate such assignment. In the event Consultant uses any individual who is not a full-time employee of Consultant or uses any other entity to perform any of the work required by Consultant hereunder, Consultant shall require said individual or entity to sign an agreement before commencing work for consultant to sign an agreement that contains identical wording to the foregoing two sentences except that the word "Consultant" shall be replaced with the individual's or entity's name.

X. CONSULTANT'S LIABILITY AND INSURANCE REQUIREMENTS

- A. The Consultant agrees to defend, at the CIRM's election, indemnify, and hold harmless the CIRM, its officers, agents, and employees from and against any and all claims, losses, expenses (including costs and reasonable attorney's fees), claims for injury, or damages that are caused by or result from the negligent or intentional acts or omissions of the Consultant, its officers, employees, or agents or Consultant's breach of this Agreement. In addition, Consultant agrees to defend, at the CIRM's election, indemnify, and hold harmless the CIRM, its officers, agents, and employees from and against any and all claims, losses, expenses (including costs and reasonable attorney's fees), claims for injury, or damages accruing or resulting to any and all contractors, subcontractors, suppliers, or any other person, firm or corporation furnishing services or supplying goods in connection with Consultant's performance of this Agreement
- B. The Consultant shall furnish a Certificate of Insurance or statement of self-insurance (contractual liability included) showing minimum coverage as follows:
 - 1. General Liability: Comprehensive or Commercial Form (Minimum Limits)

(i)	General Aggregate (BI, PD)*	\$1,000,000
(ii)	Products, Completed Operations	
	Aggregate	\$1,000,000
(iii)	Personal and Advertising Injury	\$1,000,000
(iv)	Each Occurrence	\$300,000

^{* (}not applicable to comprehensive form)

However, if such insurance is written on a claims-made form following termination of this Agreement, coverage shall survive for a period no less than three years. Coverage shall also provide for a retroactive date of placement coinciding with the effective date of this Agreement.

- 2. Business Auto Liability: (Minimum Limits) for Owned, Scheduled, Non-Owned, or Hired Automobiles with a combined single limit of no less than \$1,000,000 per occurrence.
- 3. Workers' Compensation: as required under California State Law.
- 4. Professional Liability Insurance: (Minimum Limits)

(1) Each occurrence	\$1,000,000
(2) Project Aggregate	\$2,000,000

If this insurance is written on a claims-made form, it shall continue for three years following termination of this Agreement. The insurance shall have a retroactive date of placement prior to or coinciding with the effective date of this Agreement.

5. Other insurance in amounts as from time to time may reasonably be required by the mutual consent of the CIRM and the Consultant against such other insurable hazards relating to performance.

Certificate(s) shall name the CIRM as an additional insured under 1, 2 and 4 above, obligate the insurer to notify the CIRM at least thirty (30) days prior to cancellation of or changes in any of the required insurance and include a provision that the coverage will be primary and will not participate with nor be excess to any valid and collectible insurance program of self-insurance carried or maintained by the CIRM. Premiums on all insurance policies shall be paid directly by the Consultant.

XI. RECORDS ABOUT INDIVIDUALS

- A. The Consultant acknowledges that the creation and maintenance of records pertaining to individuals is subject to certain requirements set forth by the California Information Practices Act (Civil Code 1798, et seq.) and by the CIRM policy. Such requirements include provisions governing the collection, maintenance, accuracy, dissemination, and disclosure of information about individuals, including the right of access by the subject individuals.
- B. If the Consultant creates confidential or personal records about an individual, as defined by the Information Practices Act, including notes or tape recordings, the information shall be collected to the greatest extent practicable directly from the individual who is the subject of the information. When collecting the information, the Consultant shall inform the individual that the record is being made and of the purpose of the record.

- C. Records containing confidential or personal information about individuals are the property of the CIRM and subject to the CIRM's policies and applicable federal and state laws. The Consultant agrees to deliver all such records, including originals and all copies and summaries, to the CIRM upon termination of this Agreement.
- D. The Consultant shall not use recording devices in discussions with the CIRM's employees without notifying all parties to the discussion that the discussion is being recorded.

XII. EXAMINATION OF RECORDS

The Consultant agrees that the CIRM and its authorized agents shall have the right to review and copy any records and supporting documentation pertaining to the performance of this Agreement including, but not limited to, all documents, records and work papers whether obtained or copied from the CIRM or developed by the Consultant. Consultant agrees to maintain such records for a minimum of five (5) years after final payment, unless a longer period of records retention is stipulated. Consultant agrees to allow the CIRM and its authorized agent's access to such records during normal business hours. Further, Consultant agrees to include a similar right of access in any subcontract related to the performance of this Agreement.

In accordance with state law, the Consultant agrees that the CIRM, its authorized agents, the State Controller's Office, and the Bureau of State Audits (collectively, the "Auditors") shall have the right, in connection with an audit, to review and copy any records and supporting documentation pertaining to the performance of this Agreement including, but not limited to, all documents, records and work papers whether obtained or copied from the CIRM or developed by the Consultant. Consultant agrees to maintain such records for possible audit for a minimum of five (5) years after final payment, unless a longer period of records retention is stipulated. Consultant agrees to allow the Auditors access to such records during normal business hours and to allow interviews of any employees who might reasonably have information related to such records. Further, Consultant agrees to include a similar right of the Auditors to audit records and interview staff in any subcontract related to the performance of this Agreement.

XIII. CONFLICT OF INTEREST

- A. The Consultant will not hire any officer or employee of the CIRM to perform any service covered by this Agreement. If the work is to be performed in connection with a federal or state contract or grant, the Consultant will not hire any employee of the government concerned to perform any service covered by this Agreement.
- B. The Consultant affirms that to the best of his/her knowledge there exists no actual or potential conflict between the Consultant's family, business or financial interest and the services provided under this Agreement, and in the event of change in either private interests or service under this Agreement, any question regarding possible conflict of interest which may arise as a result of such change will be raised with the CIRM.
- C. The Consultant shall not be in a reporting relationship to a CIRM employee who is a near relative, nor shall the near relative be in a decision-making position with respect to the Consultant.

XIV. AFFIRMATIVE ACTION

The Consultant recognizes that as a state government contractor or subcontractor, the Consultant is obligated to comply with all state laws and regulations regarding equal opportunity and affirmative action in government contracts. When applicable, the Consultant agrees that all such laws and their implementing regulations are incorporated herein as though set forth in full. These laws include the

nondiscrimination requirements of Government Code sections 12990 and 11135, and the nondiscrimination program and clause required by Title 2, Division 4, Chapter 5 of the California Code of Regulations.

XV. CONFIDENTIALITY

The Consultant shall keep confidential any information provided by the CIRM or any information conveyed orally to the Consultant by the CIRM with oral notification of its confidentiality (the "Confidential Information"), Consultant agrees to maintain the secrecy of CIRM's Confidential Information and agrees not to use it except in performing the Services under this Agreement and not to disclose it to anyone outside CIRM or anyone within CIRM's organization who does not have a need to know it to perform under this Agreement. This non-disclosure provision shall not apply to any of the following:

- 1. Information which the Consultant can demonstrate by written records was known to him or her prior to the effective date of this Agreement;
- 2. Is currently in, or in the future enters, the public domain other than through a breach of this Agreement or through other acts or omissions of the Consultant; or
- 3. Is obtained lawfully from a third party.

XVI. APPLICABLE LAW

The laws of the State of California shall govern this Agreement.

XVII. TERMS TO BE EXCLUSIVE

This Agreement constitutes the entire understanding between the parties regarding the subject matter hereof and supersedes any prior understanding between the parties, oral or written, regarding the same subject matter.

XVIII. WAIVER OR MODIFICATION OF TERMS

No waiver, amendment or other modifications of the terms of this Agreement shall be binding upon either party unless expressed in writing and signed by both parties hereto.

IX. STANDARD FOR PERFORMANCE

The parties acknowledge that the CIRM, in selecting the Consultant to perform the services hereunder, is relying upon the Consultant's reputation for excellence in the performance of the services required hereunder. The Consultant shall perform the services in the manner of one who is a recognized specialist in the types of services to be performed. All deadlines set forth in the Agreement are binding and may be modified only by subsequent written agreement of the parties. The Consultant shall devote such time to performance of its, her, or his duties under this Agreement as is reasonably necessary for the satisfactory performance of such duties within the deadlines set forth herein. Nothing in the foregoing shall be construed to alter the requirement that time is of the essence in this Agreement.

XX. EXCLUSION. Independent Consultant warrants that it is not excluded from participation in any governmental sponsored program, including, without limitation, the Medicare, Medicaid, or Champus programs (http://exclusions.oig.hhs.gov/search.html) and the Federal Procurement and Nonprocurement Programs (http://epls.arnet.gov/PrivacyActProvisionsEPLS.html). This Agreement shall be subject to immediate termination in the event that the Independent Consultant is excluded from participation in any federal healthcare or procurement program.

XXI RESOLUTION OF DISPUTES

If the Consultant disputes any action by the CIRM arising under or out of the performance of this contract, the Consultant shall notify the CIRM of the dispute in writing and request a claims decision. CIRM shall issue a decision within 30 days of the Consultant's notice. If the Consultant disagrees with the CIRM's claims decision, the Consultant shall submit a formal claim to the President of CIRM. The decision by the President of the CIRM shall be final and conclusive on the claim unless the decision is arbitrary, capricious or grossly erroneous or if any determination of fact is unsupported by substantial evidence. The decision may encompass facts, interpretation of the contract and determinations or applications of law. The decision shall be in writing following an opportunity for the Consultant to present oral or documentary evidence and arguments in support of the claim. Consultant shall continue with the responsibilities under this Agreement during any dispute.

INDEPENDENT CONSULTANT		THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE	
Signature	Date	Lorraine Hoffman Chief Finance & Administra	Date Officer
Name		Chief I manee & Administra	tive Officer
Title			
Social Security or Employer Identifica	tion Number*		

*Pursuant to Federal Privacy Act of 1974, you are hereby notified that disclosure of your Social Security number is mandatory. Disclosure of the Social Security number is required pursuant to Sections 6011 and 6051 of Subtitle F of the Internal Revenue Code and Regulation 4, Section 404.1256, Code of Federal Regulations, under Section 218, Title II of the Social Security Act, as amended. The Social Security number is to verify your identity. The principal uses of the Social Security number shall be to report payments you have received to the Federal and State governments.

Item 6445-502-6047001/H&S Code 125291.20/Statutes 2004/FY 06/07 Account/Fund to be charged